Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Symptomatic pineal cyst - an observational study
IRAS project ID* (or REC reference if no IRAS project ID is available):	292313
Sponsor amendment reference number*:	Amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	01 February 2022
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	Summary of the changes proposed: The study steering committee would like to include data that had been prospectively collected for clinical purposes from 21 consecutive patients with symptomatic pineal cysts who underwent resection of the symptomatic pineal operated in CUH between 1st January 2016 and 1st June 2021, i.e. the 5-year period prior to the start of the study. The cohort is clinically identical to that of the research protocol. The data collection protocol is identical relative to all primary objectives and secondary objectives 3.2.1 and 3.2.2. Data relative to the remaining secondary objectives (3.2.3, 3.2.4), and exploratory objectives (3.3.1, 3.3.2) is only partially complete. Overall, the steering committee would propose this amendment as a practically and ethically beneficial compromise to mitigate the negative impact of the COVID-19 pandemic on the current study. Purpose of the changes: The purpose of the change is to accelerate the course of the study by including data that were prospectively collected from a cohort of 21 consecutive patients treated during the 5-year period prior to the commencement of the study. The negative impact of the COVID-19 pandemic on the recruitment rate for this study has been substantial. Given the current limitations to non-urgent theatre lists, it is unlikely that the study will meet its target recruitment goal within the set 5-year timeframe. The addition of this cohort of 21 operated patients would represent half of the target study size. This would allow the study to reach completion within the proposed timeframe. Significance of the changes: The significance of the change is five-fold: (1) The amendment would mitigate the negative impact of the pandemic on the study; (2) The study participants meet all inclusion and exclusion criteria of the registered study; (3) The data collection protocol relative to the primary objectives and secondary objectives 3.2.1, 3.2.2 is identical to the registered data collection protocol; (4) The data relative to the remaining secondary objectives and exploratory objectives (3.3.1, 3.3.2) is going to be only partially complete; (5) Patients will be contacted to discuss the possibility to participate in the study and to obtain written informed consent. For detailed information about each aspect of this amendment, please refer to ‘Change 1’ below.

Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**	No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	

Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	Yes		**No**	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		**No**	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	**Yes**		No	

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will not have any additional resource implications for participating organisations - Please specify in the free text below
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Study participants: The inclusion and exclusion criteria described in the research protocol (4.1, 4.2) were already in use in the participating organisation’s clinical practice and have not changed since 1st January 2016. Therefore, the proposed clinical cohort meets all registered inclusion and exclusion criteria. Data collection: All data required to assess the primary objectives and secondary objectives 3.2.1, 3.2.2 were being collected as part of clinical care using the same protocol as the registered study protocol and will be available if patients consent for this to be used in the study. The study will terminate with N=40 as per registration. We will also evaluate the available data pertaining to the remaining secondary objectives (3.2.3, 3.2.4) and exploratory objectives (3.3.1, 3.3.2). These data will be less complete as a result of this Amendment. The steering committee is willing to accept this as a practically and ethically beneficial compromise to mitigate the impact of the COVID-19 pandemic on the study. Implementation: The change described above can be implemented within the existing resource in place at the participating organisation. The single additional requirement is to obtain written informed consent from patients who wish to be included in the study. All patients who have undergone resection of the pineal cyst since 1st January 2016 are still under active follow-up. They will be contacted via telephone by a member of the clinical care team and informed of the study and their potential role as participants. Those who express interest in participating will be sent a tailored Patient Information Sheet and consent form. They will be offered an appointment to discuss participation in person or, if they prefer, they can sign the consent form in the presence of a witness and mail it back to the research team.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	

Remove all changes below

Change 2	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)
	The study protocol has been amended to reflect the change in the study design described above. Below is the complete list of changes to the study protocol:

Further information (free text - note that this field will adapt to the amount of text entered):	above. Below is the complete list of changes to the study protocol. -Synopsis - Planned sample size -Section 4 – Project plan -Section 4.5.1 – Screening -Section 4.6 – Informed consent -Section 5 – Interventions All other sections remain unchanged.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Remove all changes below	

Change 3	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	A second Patient Information Sheet has been generated to provide tailored information to patients who are being offered participation in the study as part of the proposed amendment. Such Patient Information Sheet is identical to the one that is already registered, except for one section: -Part 1: What will happen to me if I take part? The change in the Patient Information sheet does not pose any additional burden and can be implemented within the existing resources in place at the participating organisation. Further information is provided in the “Implementation” section of Change 1.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Add another change	

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Rachel Kyd
Email address:*	rachel.kyd@addenbrookes.nhs.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies			
UK wide:	England and Wales:	Scotland:	Northern Ireland:

	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approva	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating func	HSC REC	HSC Data Guardians	Prisons	National coordinating func	Category:
Change 1:						(Y)				(Y)									C
Change 2:						(Y)				(Y)									A
Change 3:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		