Amendment Tool

v1.6 06 December 2021

For office use

QC: Yes

Section 1: Project information

Short project title*:	SWEET
IRAS project ID* (or REC reference if no IRAS project ID is available):	330129
Sponsor amendment reference number*:	SA001
Sponsor amendment date* (enter as DD/MM/YY):	02 May 2024
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)*:	Submission of the following new documents: 1. SWEET Website & expected Content www.sweetstudy.co.uk: SWEET_Website_v1.0_28Feb2024 2. SWEET recruitment animation video: SWEET_Recruitment Animation Script_v1.0_Feb2024 3. SWEET patient satisfaction score text (as per protocol): SWEET_Consultation Follow Up Text_v1.0_03Apr24 4. SWEET Baseline Questionaire Cover Letter: SWEET_BaselineCoverLetter_v1.0_03Apr24 5. SWEET Follow Up Questionaire Cover Letter: SWEET_FollowUpCoverLetter_v1.0_03Apr24 6. SWEET Patient Facing Clinic Posters: SWEET_StudyPoster_v1.0_05Mar24 7. SWEET Patient Facing Clinic Banners: SWEET_StudyBanner_v1.0_05Mar24 8. SWEET electronic questinaire cover text: SWEET_E Pro Text_v1.0_01Mar2024 Amendment to the following changing the term 'Sweet or HT&Me Study Nurse to Sweet Study Nurse/Practitioner' to highlight that intervention delivery may be delivered by a registered nurse or other healthcare professionals: 9. SWEET_Protocol_v4.0_08Apr2024 10. SWEET_ProtocolSummary_v2.0_08Apr2024 11. SWEET_PatientInformationSheet_ v4.0_03Apr2024 12. SWEET_Initial Appt Conf letter_v2.0_08Apr2024 13. SWEET_InformedConsentForm_ v4.0_03Apr2024 14. SWEET_GPLetter Usual Care_ v4.0_08Apr2024 15. SWEET_GPLetter HTMe arm_v4.0_08Apr2024 16. SWEET_FollowUpApptConfletter_v2.0_08Apr2024 17. SWEET Follow Up Questionnaire v3.0_08Apr2024 18. SA01 Cover Letter_v1.0_08Apr2024 provides additional information against the items above

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**	**Yes**	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	**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 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)
Further information (free text - note that this field will adapt to the amount of text entered):	Update to the protocol: Update the protocol to a) change contact details and b) update the terminology from Study Nurse to Study Nurse/Practitioner to appropriately define the roles of individuals who may be delivering the intervention. (SWEET_Protocol_v4.0_08Apr2024) Update to the protocol summary: Update to the protocol summary to update the terminology Study Nurse to Study Nurse/Practitioner to appropriately define the roles of individuals who may be delivering the intervention.(SWEET_ProtocolSummary_v2.0_08Apr2024)

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	**Yes**
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)*:	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	Patient Information Sheet Update to the protocol to update the terminology Study Nurse to Study Nurse/Practitioner to appropriately define the roles of individuals who may be delivering the intervention. Update to highlight utilization of a third-party application (Twilio & Firetext) to deliver SMS and emails.(SWEET_PatientInformationSheet_ v4.0_03Apr2024)- No impact PIS already in use Patient Informed Consent Form Change 1: Amalgamation of current two consent forms into one consent form for both Remote Verbal and In Person consent (improving efficiency for Participating organisations) Change 2: A guidance has been provided for site staff consenting patients. Change 3: Addition of utilization of a third-party application (Twilio & Firetext) to deliver SMS and emails. (SWEET_InformedConsentForm_ v4.0_03Apr2024) - No impact ICF already in use GP Letter: Usual Care and HT&Me

in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	GP Letter: Usual Care and HT&Me Update to both GP Letters to show change in Terminology from Study Nurse to Study Nurse/Practitioner to appropriately define the roles of individuals who may be delivering the intervention. (SWEET_GPLetter Usual Care_ v4.0_08Apr2024 & SWEET_GPLetter HTMe arm_v4.0_08Apr2024) - No impact GP Letter already in use Appointment Confirmation Letters: Initial and Follow Up Update to both Appointment Confirmation Letters to show change in Terminology from Study Nurse to Study Nurse/Practitioner to appropriately define the roles of individuals who may be delivering the intervention.(Initial Appt Conf letter_v2.0_08Apr2024 & FollowUpApptConfletter_v2.0_08Apr2024)- No impact Letters already in use Follow Up Questionnaire Update to show change in Terminology from Study Nurse to Study Nurse/Practitioner to appropriately define the roles of individuals who may be delivering the intervention (Follow Up Questionnaire v3.0_08Apr2024).- No impact Questionaires already in use

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	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 significant 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)*	SWEET_Recruitment Animation Script_v1.0_Feb2024 Patient facing recruitment animation to be hosted on SWEET website and/or Youtube and/or secure platform. No burden to participating organisation, tool to help with recruitment and study understand SWEET_BaselineCoverLetter_v1.0_03Apr24 & SWEET_FollowUpCoverLetter_v1.0_03Apr24 Supplementary Cover Letters for Paper questionaires, which sites are already managing, to assist with data retreival, (particularly Baseline questionaire) which is mandatory for randomisation SWEET_E Pro Text_v1.0_01Mar2024 No impact to site resource, patient facing material for Electronic Questionaire completion SWEET_Consultation Follow Up Text_v1.0_03Apr24 No impact to site resource, patient facing material for Patient Satisfaction Scores SWEET_StudyBanner_v1.0_05Mar24 & SWEET_StudyPoster_v1.0_05Mar24 No impact to site resource, supplementary patient facing material for study advertising SWEET_Website_v1.0_28Feb2024 No impact to site resource. For information giving only

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	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]:*	Laura Taylor
Email address:*	tnu-tr.sponsormanagement@nhs.net

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 Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	N					(Y)				(Y)				(Y)				(Y)	A
Change 2:	N					(Y)				(Y)				(Y)				N	C
Change 3:	Y					Y				Y				Y				N	C
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y				N	
Notification only:	N					N				N				N				Y	
Overall amendment type:	Substantial																		
Overall Category:	A																		