Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	BADBIR
IRAS project ID* (or REC reference if no IRAS project ID is available):	32990
Sponsor amendment reference number*:	MA July 2021
Sponsor amendment date* (enter as DD/MM/YY):	08 July 2021
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)*:	In 2020 there was s Substantial Amendment approved for BADBIR, an observational study following outcomes for psoriasis patients receiving new treatments. One part of this was to allow data collection directly from study participants through a dedicated electronic portal (website or app). This "Patient Portal" has been piloted in a small number of sites and feedback indicates that contacting registered BADBIR participants outside of clinic appointments would be beneficial for clinical/research teams to encourage engagement. This amendment seeks to add to study procedure for sites to optionally contact existing participants outside of routine clinic attendance requesting participation in the Portal.

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 ○
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 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:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☑	☑	☑
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☑	☑	☑

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, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Participant Procedures
Specific change (select - only available when area of change is selected first)*:	Participant procedures - minor change that can be implemented within existing resource at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	To encourage participation from registered BADBIR participants in a electronic questionnare entry, local research teams may optionally contact patients. This will allow the research teams at study sites to make contact outside of the dermatology outpatients clinic to request use of the BADBIR Portal to record study questionnaires. All local research teams are healthcare professionals and able to tailor communicatiosn appropritely. Supporting information on process for Portal registration and data completion is available on the BADBIR website for guidance. This additional optional procedure will provide the local research teams with more tools to increase participation in the BADBIR Portal. To confirm; only those already consented into the study will be contacted by the local research teams, there will be no confidentiality implications as the local research teams already have access to their personal information with consent. The wording used to contact the participants will be reasonably adapted from documentation already approved by the REC for this purpose only.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
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]:*	Lynne MacRae
Email address:*	FBMHethics@manchester.ac.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:			
	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	CAC	Confirmation Assurance	HRW Governance	(MCA)		PS	and HCRW Approval	(AWIA)		(RAEC)	onal coordinating function	REC	Data Guardians		onal coordinating function

	REC	Com MHR	Com MHR	ARSA	Radia	UKSV	REC	CAG	HMP	HRA	REC	PBPI	SPS	Natio	HSC	HSC	Priso	Natio	Category:
Change 1:						(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:						N				N				N				N	
Notification only:						Y				Y				Y				Y	
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	C																		