Amendment Tool

v1.2 11 Jun 2020

For office use

QC: Yes

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*:	SA12, 01/07/2020
Sponsor amendment date* (enter as DD/MM/YY):	01 July 2020
Summary of amendment including justification*:	Changes are required to data collection items for the BADBIR study. This is an observational post-marketing drug safety study collecting real world data from outpatients clinics at NHS and other hospital sites. Due to COVID-19, many clinic appointments now take place remotely via phone or video. This is anticipated to continue post-pandemic thus changes are required to ensure the study can continue to collect appropriate data to answer questions on long-term saftey and effectivenss of new treatments for psoraisis. Additionally, the amendment also includes updated consent materials to stregthen adherence to GDPR. A bundle of minor changes and clarifications to the protocol have also been made.

Project type:	◉ 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?:	◉ 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?	○ 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 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 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 Changes" tab. To add another change, tick 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)*:	Data collection, transfer or processing of identifiable participant information - Changes in arrangements or organisations involved (other than the addition of new participating organisations)
Further information (free text):	To adapt to the scenario described in the amendment justification, the BADBIR study will make available: (1) Alternative form of data collection directly from patients. Web or app entry of existing study questionnaires (2) Alternative patient-assessed version of primary disease severity measures added to protocol (SAPASI and PGA) (3) Alteration to existing Patient Invitation Letter to clarify postal consent process (previously approved by Ethics at substantial amendment 5). Please also see change #5. The study protocol, invitation letter and system level security policy+M107 document (SLSP) are amended to describe these changes.

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?:	◉ All		○ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	GDPR wording - Accepted wording used verbatim
Further information (free text):	Minor amendments to Patient Information Sheet to increase detail on governance items as GDPR guidance has matured. Existing participants are not required to re-consent as headline verison (5) of PIS has not changed.

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?:	◉ All		○ Some	

Add another change: ☑

Change 3	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	CRF/other study data records - Changes in the documentation used by the research team for recording study data
Further information (free text):	Supporting offline CRF and questoinnares are updated inline with the changes made to protocol

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?:	◉ All		○ Some	

Add another change: ☑

Change 4	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below

Further information (free text):	A bundle of minor changes and clarifications have been made to the protocol in addition to the chages described in #1. This includes: ● Updated list of Steering Committee membership ● Up-to-date licenced treatments for psoriasis ● Small clarification to critera for Small Molecule cohort recruitment. ● Clarification that analysis can be intra-biologic treatments and not solely between cohorts These changes do not alter the study design or activities at sites.

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?:	◉ All		○ Some	

Add another change: ☑

Change 5	
Area of change (select)*:	Participant Procedures
Specific change (select - only available when area of change is selected first)*:	Recruitment - Change in identification, approach, recruitment or consent of participants
Further information (free text):	With clinic appointments now taking place mainly remotely, in-person consent will not be feasible. As outlined in #1, the Participant Invitation Letter has been updated in expectation that postal consent will become more common. Where local arrangments allow, return of scanned consent forms from a participant to their local study teams would be possible. An optional paragraph has been included within the Invitation Letter to accomdate.

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?:	◉ 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 PDF copy of the completed amendment tool that can 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, refer to the "Submission Guidance" tab for 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:					
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	REC	Competent Auth MHRA - Medicin	Competent Auth MHRA - Device:	ARSAC	Radiation Assur	UKSW Governa	REC (MCA)	CAG	HMPPS	HRA and HCRV	REC (AWIA)	PBPP	SPS (RAEC)	National coordir	HSC REC	HSC Data Guar	Prisons	National coordir	Category:
Change 1:	N					Y				Y				Y				Y	A
Change 2:	N					N				N				N				N	N/A
Change 3:	N					(Y)				(Y)				(Y)				(Y)	A
Change 4:	N					(Y)				(Y)				(Y)				(Y)	C
Change 5:	Y					Y				Y				Y				Y	A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y				Y	
Notification only:	N					N				N				N				N	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		