

Partner Organisations:

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/> . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	A multi-centre, prospective, cohort study to establish clinically relevant pharmaco-genetic markers of systemic treatment outcomes in patients with severe psoriasis
IRAS Project ID:	71048
Sponsor Amendment Notification number:	MA12
Sponsor Amendment Notification date:	19.06.2019
Details of Chief Investigator:	
Name [first name and surname]	Professor Catherine Smith
Address:	St John's Institute of Dermatology, Guy's and St Thomas' NHS Trust Guy's Hospital
Postcode:	SE1 9RT
Contact telephone number:	Direct: 020 718 86410 // PA: Ediz 020 7188 6412
Email address:	Catherine.smith@kcl.ac.uk / Catherine.smith@gstt.nhs.uk
Details of Lead Sponsor:	
Name:	Guys & St Thomas' NHS Foundation Trust
Contact email address:	R&D@gstt.nhs.uk
Details of Lead Nation:	
Name of lead nation <i>delete as appropriate</i>	England / Northern Ireland / Scotland / Wales
If England led is the study going through CSP? <i>delete as appropriate</i>	N/A
Name of lead R&D office:	Guys & St Thomas' NHS Foundation Trust

Partner Organisations:

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), including version numbers <i>(please ensure all referenced supporting documents are submitted with this form)</i>		R&D category of amendment <i>(category A, B, C)</i> <i>For office use only</i>
		Nation	Sites	Document	Version	
1	Study extension to 31 st March 2024	All	All	n/a	n/a	
2	Opening of 2 new sites	England	Epsom and St Helier University Hospitals NHS Trust (PI Dr Juliet Williams) Blackpool Teaching Hospitals NHS Trust (PI Sr Melanie Caswell)	OID	V1	
3	Dr Alexa Shipman will take over as PI from Dr Hywel Cooper	England	Portsmouth Hospitals NHS Trust	n/a	n/a	
4	Joanne Topliffe will take over as PI from Dr Davide Altamura	England	Mid Essex Hospital Services NHS Trust	n/a	n/a	

[Add further rows as required]

Partner Organisations:

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

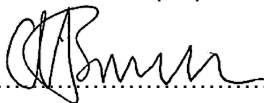
NISCHR Permissions Co-ordinating Unit, Wales

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator:



Print name:

Prof Catherine Smith

Date:

04.07.2019

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative:



Print name: Elizabeth Bruna

Post: Acting R&D Manager Non-Commercial

Organisation: Guy's and St. Thomas' NHS Foundation Trust

Date: 04/07/2019