

London - Westminster Research Ethics Committee

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05 July 2019

Dr Alice Russell
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Dear Dr Russell

Study title: A multi-centre, prospective, cohort study to establish clinically relevant pharmaco-genetic markers of systemic treatment outcomes in patients with severe psoriasis

REC reference: 11/H0802/7

Amendment number: 5 - 02/05/2019

Amendment date: 06 June 2019

IRAS project ID: 71048

- 1) background and rationale updated
- 2) trial study design updated
- 3) updated linkage to BADBIR
- 4) new section to explain inclusion of PSORT participants
- 5) updated subjects criteria
- 6) clarification re participants may be recalled for further sampling
- 7) updated investigational plan
- 8) clarification on anon and data management
- 9) increased sample size
- 10) updated safety reporting requirements
- 11) deleted appendices from protocol

Thank you for submitting the above amendment, which was received on 03 May 2019. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|--|----------------|-----------------|
| Copies of advertisement materials for research participants [BSTOP_Poster_v1_31Jan19] | 1 | 31 January 2019 |
| Covering letter on headed paper [BSTOP_SA05_CoverLetter] | | 06 June 2019 |
| Letters of invitation to participant [BSTOP Patient invite letter v2 31Jan19_track] | 2 | 31 January 2019 |
| Letters of invitation to participant [BSTOP Patient invite letter v2 31Jan19_clean] | 2 | 31 January 2019 |
| Notice of Substantial Amendment (non-CTIMP) [NoSA_SA05_BSTOP_0606] | 5 - 02/05/2019 | 06 June 2019 |
| Participant consent form [BSTOP ICF v5 01Mar19_clean] | 5 | 01 March 2019 |
| Participant consent form [BSTOP ICF v5 01Mar19_tracked] | 5 | 01 March 2019 |
| Participant consent form [Withdrawal of consent v2 31Jan19_clean] | 2 | 31 January 2019 |
| Participant consent form [Withdrawal of consent v2 31Jan19_tracked] | 2 | 31 January 2019 |
| Participant information sheet (PIS) [BSTOP PIS v5 01Mar19_clean] | 5 | 01 March 2019 |
| Participant information sheet (PIS) [BSTOP PIS v5 01Mar19_tracked] | 5 | 01 March 2019 |
| Participant information sheet (PIS) [BSTOP Skin ICF v5 31Jan19_clean] | 1 | 31 January 2019 |
| Research protocol or project proposal [BSTOP Protocol v6_20190606_clean] | 6 | 06 June 2019 |
| Research protocol or project proposal [BSTOP Protocol v6_20190606_tracked] | 6 | 06 June 2019 |

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

11/H0802/7:

Please quote this number on all correspondence

Yours sincerely



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