



London - Westminster Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

17 July 2019

Dr Alice Russell
Clinical Trial Research Manager
Guy's and St Thomas' NHS Foundation Trust
Skin Therapy Research Unit
St John's Institute of Dermatology
9th Floor Tower Wing
Guy's Hospital, Great Maze Pond
London
SE1 9RT

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

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

SG24/07/19 Revised to include updated vers Skin ICF.

The Committee requested that the PIS indicated to participants volumes of blood in ml and teaspoons as well as how much blood they will give in total if giving the additional amounts and how this compared to a standard blood donor.

Catherine Smith provided revised PISs.

The Committee accepted the documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<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 v2.1 16Jul19_clean]	2.1	16 July 2019
Notice of Substantial Amendment (non-CTIMP) [NoSA_SA05_BSTOP_0606]	5 - 02/05/2019	06 June 2019
Participant consent form [BSTOP ICF v5 .1 16Jul19_clean]	5.1	16 July 2019
Participant consent form [Withdrawal of consent v2.1 16Jul19_clean]	2.1	16 July 2019
Participant consent form [BSTOP Skin ICF v5.1 16Jul19_clean]	1.1	16 July 2019
Participant information sheet (PIS) [BSTOP PIS v5.1 16Jul19_tracked]	5.1	16 July 2019
Participant information sheet (PIS) [BSTOP PIS v5.1 16Jul19_clean]	5.1	16 July 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

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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

A handwritten signature in black ink, appearing to read 'R. Goldstein', with a stylized flourish at the end.

Mr Robert Goldstein
Chair

E-mail: nrescommittee.london-westminster@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Catherine Smith, Guy's & St. Thomas' NHS Foundation Trust

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Attendance at Sub-Committee of the REC meeting on 08 July 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Katila George	Senior Clinical Research Nurse	Yes	
Mr Robert Goldstein	Chair - Economist	Yes	Meeting Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Sarah Graves	Approvals Officer