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Health Research Authority
NRES Committee London – Westminster

RE: Biomarkers of Systemic Treatment Outcomes in Psoriasis (BSTOP)
REC: 11/0802/7

Dear Robert Goldstein, Chair
Sarah Graves, Manager

I am writing to request ethical approval for substantial amendments to the above study, the full details of which are summarised in the accompanying Notice of Substantial Amendment form.

To summarise the main issues detailed in the substantial amendment:

(i) We have updated our study protocol to:

a. Provide further clarity on the existing study design, patient cohorts and schedules
b. Extend our inclusion criteria in recognition of progress made in relation to treatment options for psoriasis
c. Include additional sampling methods for (i) recall of patients and (ii) to allow for more comprehensive sample collection of skin and blood in the first 12-16 weeks post-drug start in a subset of patients
d. Extend the period over which a patient may be seen
e. Increase patient recruitment for the duration of the study, in light of additional funding received (will subsequently be extended to 31st March 2024, contractual changes pending mean this is not included here), opportunities for collaboration past and present, and the increased number of drugs now available
f. Give more explicit detail and transparency over data and sample management practice, to ensure compliance with General Data Protection Regulation
g. Retain study data and samples following withdrawal of patients

(ii) We have updated the current patient information in line with the changes to the protocol listed above, and to provide further clarity for patients as to whether they will be invited to participate in a one-off visit, or provide additional samples during treatment

Yours sincerely,

Professor Catherine Smith, Chief Investigator