

Health Research Authority

East of England - Cambridge South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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.

02 November 2018

Dr Gideon Hirschfield
Centre for Liver Research
Institute of Biomedical Research
College of Medical & Dental Sciences
B15 2TT

Dear Dr Hirschfield,

| | |
|--------------------------|---|
| Study title: | A UK Collaborative Study to Determine the Genetic Basis of Primary Sclerosing Cholangitis (UK-PSC) |
| REC reference: | 08/H0305/45 |
| Amendment number: | Amendment 5 |
| Amendment date: | 08 March 2018 |

The above amendment was reviewed on 02 November 2018 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.

The members of the Sub-Committee were in agreement that the Substantial Amendment did not raise any material ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|-----------------|
| Covering letter on headed paper | | 10 October 2018 |
| GP/consultant information sheets or letters [UK PSC Clinician questionnaire cover letter (adult) version 4] | 4 | 08 March 2018 |

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| GP/consultant information sheets or letters [UK PSC GP Information Sheet (adults) version 3] | 3 | 08 March 2018 |
| GP/consultant information sheets or letters [UK PSC Resampling - clinician questionnaire cover letter] | 1 | 08 March 2018 |
| GP/consultant information sheets or letters [UK PSC Resampling - letter to GP v2] | 2 | 08 March 2018 |
| Letter from sponsor [PSC Support letter of support 050218] | | 05 February 2018 |
| Letters of invitation to participant [UK PSC - Participant Reconsenting letter v2] | 2 | 08 March 2018 |
| Letters of invitation to participant [UK PSC - Participant Resampling letter - DNA v1] | 1 | 08 March 2018 |
| Letters of invitation to participant [UK PSC - Participant Resampling letter - Serum v1] | 1 | 08 March 2018 |
| Letters of invitation to participant [UK PSC Invitation to Participant - version 5] | 5 | 08 March 2018 |
| Letters of invitation to participant [UK PSC Letter to Participant version 5] | 5 | 08 March 2018 |
| Letters of invitation to participant [UK PSC Participant Clinical Trials invitation - adults v1] | 1 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Clinical Data Update Questionnaire version 1] | 1 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Clinician questionnaire version 4] | 4 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Paediatric Clinician Questionnaire v1] | 1 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Paediatric Participant Questionnaire version 1] | 1 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Participant Questionnaire v3] | 3 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Pruritus Questionnaire A] | 3 | 08 March 2018 |
| Non-validated questionnaire [UK PSC Pruritus questionnaire B] | 3 | 08 March 2018 |
| Notice of Substantial Amendment (non-CTIMP) | Amendment 5 | 08 March 2018 |
| Other [Appendix D - UK PSC Paediatric Reconsent and Resampling v1] | 1 | 08 March 2018 |
| Other [APPENDIX E - UK PSC Digital Datasets] | 1 | 08 March 2018 |
| Other [BLISS Opt-out-form] | | |
| Other [BLISS Study - HSCIC opt-out letter v2 110214] | 2 | 11 February 2014 |
| Other [UK PSC Study - Site and PI changes @ Oct 2018] | | |
| Other [Email from Outgoing CI to New CI] | | 10 October 2018 |
| Other [Original IRAS Form Signed by New CI] | | |
| Other [Palak Trivedi GCP] | | |
| Other [UK PSC GDPR Transparency Info (For Website)] | 1 | 17 August 2018 |
| Other [UK PSC GDPR Transparency Info (Sent with PIS)] | 1 | 17 August 2018 |
| Other [UK PSC Health and Social Care Board Northern Ireland Opt-out-form] | 1 | 08 March 2018 |
| Other [UK PSC NHS Digital Opt-out-form] | 1 | 08 March 2018 |
| Other [UK PSC NHS National Services Scotland Opt-out-form] | 1 | 08 March 2018 |
| Other [UK PSC NHS Wales Informatics Service Opt-out-form] | 1 | 08 March 2018 |
| Other [UK PSC Participant Information Letter - England] | 1 | 08 March 2018 |
| Other [UK PSC Participant Information Letter - Northern Ireland] | 1 | 08 March 2018 |
| Other [UK PSC Participant Information Letter - Scotland] | 1 | 08 March 2018 |
| Other [UK PSC Participant Information Letter - Wales] | 1 | 08 March 2018 |

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|---|---|---------------|
| Participant consent form [OLD - UK PSC Parent Guardian ICF - v2] | 2 | |
| Participant consent form [UK PSC Child Assent Form V2] | 2 | 08 March 2018 |
| Participant consent form [UK PSC ICF v4] | 4 | 08 March 2018 |
| Participant consent form [UK PSC Parent Guardian ICF - v2] | 2 | 08 March 2018 |
| Participant information sheet (PIS) [UK PSC Parent Guardian PIS - v2] | 2 | 08 March 2018 |
| Participant information sheet (PIS) [UK PSC PIS age 11-15 years - Version 1] | 1 | 08 March 2018 |
| Participant information sheet (PIS) [UK PSC PIS age 6-10yrs v2] | 2 | 08 March 2018 |
| Participant information sheet (PIS) [UK PSC PIS age 16-17 yrs - v1] | 1 | 08 March 2018 |
| Participant information sheet (PIS) [UK PSC PIS version 7] | 7 | 08 March 2018 |
| Research protocol or project proposal [UK PSC Protocol v5] | 5 | 08 March 2018 |
| Summary CV for Chief Investigator (CI) [Palak Trivedi Curriculum Vitae 2018-08] | | |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Appendix A - UK PSC Participation Flow Chart - Adults - version 3] | 3 | 08 March 2018 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Appendix B - UK PSC Participation Flow Chart - children v2] | 2 | 08 March 2018 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [APPENDIX C - UK PSC Participation Flow Chart - Adult Reconsenting and Resampling - version 2] | 2 | 08 March 2018 |

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

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|---------------------|---|
| 08/H0305/45: | Please quote this number on all correspondence |
|---------------------|---|

Yours sincerely,

P. P. 

Dr Leslie Gelling
Chair

E-mail: nrescommittee.eastofengland-cambridgesouth@nhs.net

Reissue to correct documents table
KL 16.11.2018

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

Copy to: Dr Gideon Hirschfield, NIHR Centre for Liver Research

East of England - Cambridge South Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 02 November 2018

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|--------------------|-------------------------------|----------------|--------------|
| Dr Leslie Gelling | Reader in Research Ethics | Yes | |
| Dr Michael Sheldon | Retired Clinical Psychologist | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|-------------|---|
| Kate Loven | REC Assistant |