

**West Midlands - Black Country 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 April 2019

Mrs Jane Prewett  
University of Warwick  
Kirby Corner Road  
Coventry  
CV48UW

Dear Mrs Prewett

|                          |  |
|--------------------------|--|
| <b>Study title:</b>      | <b>Achilles Tendinopathy Management (ATM): A multi-centre placebo controlled randomised controlled trial comparing Platelet Rich Plasma (PRP) to placebo (imitation) injection in adults with Achilles tendon pain</b> |
| <b>REC reference:</b>    | <b>15/WM/0359</b>  |
| <b>Amendment number:</b> | <b>Amendment 18</b>  |
| <b>Amendment date:</b>   | <b>13 March 2019</b>   |
| <b>IRAS project ID:</b>  | <b>187315</b>  |

The above amendment was reviewed on 29 March 2019 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.

Discussion: There were no ethical concerns raised.

**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 [PRP Analysis advert V1 13_03_2019]             | 1              | 13 March 2019 |
| Covering letter on headed paper [Ethics cover letter]   |                | 14 March 2019 |
| GP/consultant information sheets or letters [Health professional Email ATM]                                 | 1              | 13 March 2019 |
| Letters of invitation to participant [EMAIL Template for Analysis of PRP advert]                            | 1              | 13 March 2019 |
| Notice of Substantial Amendment (non-CTIMP)   | Amendment 18   | 13 March 2019 |
| Participant consent form [ATM Consent Form v1 13_03_2019Final.]   | 1              | 13 March 2019 |
| Participant information sheet (PIS) [ATM Participant information sheet Analysis of PRP study v1 13_03_2019] | 1              | 13 March 2019 |
| Research protocol or project proposal [ATM Protocol v11 Final]  | 11             | 13 March 2019 |
| Research protocol or project proposal [ATM Protocol v11 tracked.]   | 11             | 13 March 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/>

|                    |   |
|--------------------|---|
| <b>15/WM/0359:</b> | <b>Please quote this number on all correspondence</b> |
|--------------------|---|

Yours sincerely

PP



**Dr Hilary Paniagua**  
**Chair**

E-mail: [nrescommittee.westmidlands-blackcountry@nhs.net](mailto:nrescommittee.westmidlands-blackcountry@nhs.net)

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

*Copy to: Dr Rebecca Kearney, University of Warwick*

**West Midlands - Black Country Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 29 March 2019**

**Committee Members:**

| <i>Name</i>             | <i>Profession</i>   | <i>Present</i> | <i>Notes</i> |
|-------------------------|---|----------------|--------------|
| Dr Joseph Arumainayagam | Consultant and Honorary Senior Clinical Lecturer in HIV and GUM | Yes            |              |
| Dr Hilary Paniagua      | Senior Lecturer   | Yes            |              |

**Also in attendance:**

| <i>Name</i>   | <i>Position (or reason for attending)</i> |
|---------------|---|
| Mr David Parr | Approvals Administrator                   |