

West Midlands - The Black Country Research Ethics Committee  
Royal Standard Place  
Nottingham  
NG1 6FS

Date: 29/03/2016

Dear Dr Hilary Paniagua,

**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**

**REC reference: 15/WM/0359**

**IRAS project ID: 187315**

I am writing to you on behalf of the Chief Investigator of the ATM trial, Dr Rebecca Kearney as we would like to submit Amendment 2 for the opinion of the ethics committee.

This amendment includes the following:

- New documents:
  - **ATM PIS Postal Cover letter v1 11-JAN-2016**
- Change to the following documents:
  - **ATM Protocol v3 03-MAR-2016**
  - **ATM Patient information sheet - Summary v4 01-MAR-2016**
  - **ATM Patient information sheet - Full v6 23-MAR-2016**
  - **ATM Consent Form v4 23-MAR-2016**
  - **ATM 6 Month Questionnaire Cover Letter v 3.0 21-MAR-2016**
  - **ATM Baseline Participant Questionnaire v2 01-MAR-2016**
  - **ATM 2 week Follow up CRF v2 01-MAR-2016**
  - **ATM 3 month Participant Questionnaires v2 01-MAR-2016**
  - **ATM 6 month Participant Questionnaires v3 21-MAR-2016**

The documents have been accompanied with track changed documents for ease of identifying the amendments made. The following documents could not be track to reflect the changes so are listed below:

- **ATM Baseline Participant Questionnaire v2 01-MAR-2016** – addition of terms to the glossary and instructions on second page, re-order of the questionnaires (VISA-A now appears first as this is the primary outcome). Addition of VAS scale to collect pain scores. Re-wording of last page to provide clearer information to the participant.
- **ATM 2 week Follow up CRF v2 01-MAR-2016** – rewording of some of the questions so that these are more understandable to the lay person.
- **ATM 3 month Participant Questionnaires v2 01-MAR-2016** – addition of terms to the glossary and instructions on second page, re-order of the questionnaires (VISA-A now appears first as this is the

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primary outcome). Addition of VAS scale to collect pain scores. Rewording of last page to provide clearer information to the participant. Rewording of some of the questions on the complications form in the booklet so that these are more understandable to the lay person.

- **ATM 6 month Participant Questionnaires v3 21-MAR-2016** – addition of terms to the glossary and instructions on second page, re-order of the questionnaires (VISA-A now appears first as this is the primary outcome). Addition of VAS scale to collect pain scores. Rewording of last page to provide clearer information to the participant. Rewording of some of the questions on the complications form in the booklet so that these are more understandable to the lay person.

Thank you and please do not hesitate to contact us immediately if there is further information you require.

Yours sincerely,  
Dr Joanne O'Beirne-Elliman

On behalf of **Dr Rebecca Kearney**

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