FACET INJECTION STUDY

PATIENT ENROLMENT

INSTRUCTION TO SITE: Upon completion of diagnostic assessment, confirmation of patient eligibility following diagnostic assessment and written informed consent obtained from the patient, please complete the following **sections A and B** and telephone Warwick Clinical Trials Unit on 02476 150402 or fax the form to 02476 151586 (Monday to Friday 09:00 – 17:00) to obtain a 'Unique Participant Trial ID' number. Upon confirmation, add the 'Unique participant trial ID' and the 'enrolment date' within **section C** of the form. Upon completion of the form please fax to FIS study team (fax number 02476 151136) and retain the completed form with the participant's Consent Form in the participant's case report form.

SITE NAME/SITE ID:	Caller's Name:	Caller's TELEPHONE No:	Caller's FAX No:

A: Participant details

1. **Participant initials:** ☐☐☐ 2. **Participant Gender:** ☐ Male ☐ Female
3. **Participant Date of Birth:** d d - m o n - y y y y
4. **Age group:** ☐ 18-49 ☐ 50 and over
5. **NHS number:** ☐☐☐☐☐☐☐☐☐☐
6. **Hospital number:** ☐☐☐☐☐☐☐☐☐☐

B: Participant Eligibility

1. **Date of diagnostic assessment:** d d - m o n - y y y y
2. **Troublesomeness reported at diagnostic assessment:** ☐ Moderately ☐ Very ☐ Extremely
3. **Does the participant meet all the eligibility criteria?** ☐ Yes ☐ No
4. **Has the eligibility page within the CRF been completed and signed off?** ☐ Yes ☐ No
5. **Has the participant signed study informed consent form?** ☐ Yes ☐ No
6. **Date trial consent form signed by participant:** d d m o n y y y y
7. **Scheduled date of First BUC Treatment Session :** d d - m o n y y y y
8. **Will the participant be using text messaging:** ☐ Yes* ☐ No

*If yes, Participant mobile phone number: 0 7 ☐☐☐☐☐☐☐☐☐

* If yes, Participant preferred name:
For the purpose of text message opener- free text [50 characters]

Participant enrolled by:

Name :			
Signature :		Date signed:	DD – MON-YYYY

C. Unique Participant Trial ID Allocation (Site add to the form and fax to FIS Study Team 02476 151136)

UNIQUE PARTICIPANT TRIAL ID: 0 ☐☐☐

Date of Enrolment: d d m o n y y y y

INSTRUCTIONS TO SITE : Enter the unique participant trial ID number onto all enrolled participant's study related documentation (ie questionnaires, screening log, consent form, baseline questionnaire, case report form).

PLEASE ENSURE THE PARTICIPANT CONTACT DETAILS FORM IS COMPLETED FAXED TO FIS TEAM, fax 02476 151136.

INSTRUCTION TO SITE: This form is to be completed at same time as enrolment form

FACET INJECTION STUDY

Site ID: ☐☐☐☐☐

Participant Trial ID: ☐☐☐☐

Participant Contact Details Form

☐ Initial contact details form ☐ Revised contact details form

DO NOT SEND THIS PAGE WITH THE PATIENT CASE REPORT FORMS (CRFs)

Please fax to FIS Study Team 02476 151136 once written consent provided

Title: ☐ Mr ☐ Mrs ☐ Miss ☐ **Other**, specify: .....

First Name: ..... **Surname**: .....

House/Flat Number: ..... **Telephone**

Street name: ..... Home: .....

..... Work: .....

Town/City: ..... Mobile: 0 7 ☐☐☐☐☐☐☐☐☐

Postcode: .....

Email: ..... @.....

Will the participant be using text messaging ? ☐ **Yes** ☐ **No**

Has the participant given consent to be interviewed (process evaluation) ? ☐ **Yes** ☐ **No**

GP DETAILS

Surgery Name: .....

Postcode ..... Telephone: .....

Form completed by :

Name: .....

Investigator/Research Physiotherapist signature: .....

Date : ☐☐ - ☐☐☐ - ☐☐☐☐

FACET INJECTION STUDY

RANDOMISATION FORM

INSTRUCTION TO SITE: To randomise a participant, please complete this form and telephone Warwick Clinical Trials Unit Randomisation Service 02476 150402, or fax to 02476 151586 (Monday to Friday 09:00 – 17:00), providing responses to questions within this form.

SITE NAME/SITE ID:	Caller's Name:	Caller's TELEPHONE No:	Caller's FAX No:

A: Participant details

1. **Unique Participant Trial ID :** ☐☐☐☐
2. **Participant Initials:** ☐☐☐
3. **Participant Date of Birth:** d d m o n y y y y
4. **Gender:** ☐ **Male** ☐ **Female**

B. PARTICIPANT ELIGIBILITY RECONFIRMATION :

1. **Actual date of first BUC treatment session:** d d m o n y y y y

C. Details of Site personnel completing randomisation

Name :			
Signature :		**Date signed:**	DD – MON-YYYY

D. TO BE COMPLETED BY SITE PERSONNEL AFTER RANDOMISATION

WCTU RANDOMISATION SERVICE WILL PROVIDE THE CALLER WITH THE ALLOCATION AT TIME OF TELEPHONE CALL AND PROVIDE CONFIRMATION VIA EMAIL TO SITE PERSONNEL COMPLETING RANDOMISATION.

PARTICIPANT RANDOMISED TO : ☐ **INJECTION + BEST USUAL CARE** ☐ **BEST USUAL CARE ONLY**

Actions to be completed by site:

- ☐ Letter confirming trial appointments provided to participant.
- ☐ Check participant's contact details. If details have changed, please complete and fax updated version to FIS Study team (fax 02476 151136).
- ☐ **Please ensure fully completed form is faxed to FIS Study Team fax 02476 151136 after randomisation is completed. Please retain the original completed form in the participants Case Report Form.**