Patient Hospital Number

SCIATiC

SubCutaneous Injection of Adalimumab Trial Compared with Control

[redacted]

Date of Call: ☐☐ ☐☐ ☐☐☐☐

DD **MM** **YYYY**

Time of Call: ☐☐ ☐☐

Hrs **mins**

Name of Caller: _____

Is the patient experiencing any of the following?

Please check these inclusion criteria for the participant and tick the appropriate box for each row:

		YES	NO
1	Are they aged 18 years or older?		
2	Current leg pain worse than, or as bad as, back pain		
3	Unilateral leg pain approximating a dermatomal distribution (contralateral buttock pain permitted if it does not extend below the inferior gluteal margin)		
4	Have they had persistent symptoms of the above for less than 22 weeks?		
5	Are they using a method of contraception? *(please note women who are pre-menopausal or not surgically sterile, must have a negative pregnancy test within two weeks of entering the trial)*		

Please check these exclusion criteria for the participant and tick the appropriate box for each row:

		YES	NO
6	Have their Sciatica symptoms persisted for longer than six months?		
7	Prior use of biological agents targeting TNF-alpha within the previous six months?		
8	Previous spinal surgery?		
9	Contra-indications to adalimumab injection including serious infection such as active or latent tuberculosis, transplanted organ, demyelinating disorders, malignancy, cardiac failure?		
10	Contra-indications to MRI including metal implants, potential metallic intra-ocular foreign bodies, claustrophobia?		
11	Pregnant, possibly pregnant or lactating?		
12	Unable to communicate in English or Welsh?		
13	Widespread pain throughout the body including the upper limb? *(Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present).*		

If the participant answers **YES** to question 1 to 5 then invite to clinic for eligibility check, consenting and screening, if participant answers **Yes** to Question 6 to 13 then participant is excluded.

Is the participant eligible? Yes ☐ No ☐

Participants Date of Birth ☐☐ ☐☐ ☐☐☐☐

DD **MM** **YYYY**

Date of 1st clinical appointment assessment screening:

☐☐ ☐☐ ☐☐☐☐

DD **MM** **YYYY**

Participant Identification Number

SCIATiC

SubCutaneous Injection of Adalimumab Trial Compared with Control

CASE REPORT FORM

[redacted]

CRF Completion Instructions for researchers

General

Complete the CRF using a **ballpoint pen** and ensure that all entries are complete and legible.

Avoid the use of abbreviations and acronyms.

The CRF should be completed as soon as possible after the scheduled visit.

Do not use subject identifiers anywhere on the CRF, such as name, hospital number etc., in order to maintain the confidentiality of the participant. Ensure that the header information (i.e. participant identification number) is completed consistently throughout the CRF.

Each CRF page should be signed and dated by the person completing the form.

The 'completed by' Name in the footer of each page must be legible and **CRFs should only be completed by individuals delegated to complete CRFs on the Site Delegation log (and signed by the PI).**

Ensure that all fields are completed on each page:

- If a test was Not Done record **ND** in the relevant box(es)
- Where information is Not Known write **NK** in relevant box(es)
- Where information is not applicable write **NA** in the relevant box(es)

Corrections to entries

If an error is made, draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.

Do NOT

- Obscure the original entry by scribbling it out
- Try to correct/ modify the original entry
- Use Tippex or correction fluid

Medications taken by the participant during the trial should be recorded on the "Concomitant Medications Log" using the generic name whenever possible, except combination products which will be recorded using the established trade name. All non-IMPs mentioned in the protocol should also be recorded on the "Concomitant medication Log" for the duration of the trial.

Verbatim Adverse Event terms (initial medical term) should be recorded as the final diagnosis whenever possible.

Complete all **dates** as day, month, year i.e. 13/11/2008. Partial dates should be recorded as NK/11/2008.

All **times** are to be recorded in 24 hour format without punctuation and always use 4-digits; i.e. 0200 or 2130. Midnight is recorded as 0000.

Weights should be recorded to the nearest 0.1 kg.

Source documents such as lab reports, ECG reports etc. should be filed separately from the CRF (if not in the medical notes) for each participant and be signed and dated by a delegated Investigator as proof of review of the assessment during the trial

If a subject prematurely withdraws from the trial a single line must be drawn across each uncompleted page to correspond with the last visit of the subject as mentioned on the "Trial Completion" page.

The Chief Investigator (for lead site)/Principal Investigator is responsible for the accuracy of the data reported on the CRF. The CI/PI must sign and date the Principal Investigator's Sign Off (below) to certify accuracy, completeness and legibility of the data reported in the CRF.

Serious Adverse Events (SAEs)

SAEs should be emailed **within 24 hours** of the site being aware of the event using the trial specific SAE report form **emailed toSCIATiCSAE@bangor.ac.uk**

Storage

CRF documents should be stored in a locked, secure area when not in use where confidentiality can be maintained. Ensure that they are stored separately to any other documents that might reveal the identity of the participant

Participant Identification Number ☐☐☐☐☐☐☐

FIRST CLINICAL ASSESSMENT DEMOGRAPHIC DATA

Date of Assessment:

☐☐ ☐☐ ☐☐☐☐

(DD/MM/YYYY)

Informed Consent:	
Date participant signed written consent form 1: ☐☐ ☐☐ ☐☐☐☐ (DD / MM / YYYY)	**Date of first trial-related procedure:** ☐☐ ☐☐ ☐☐☐☐ (DD / MM / YYYY)
Name of person taking informed consent: _____	
Please give a copy of the Participant Information Sheet and signed copy of the informed consent form to the participant; a copy for the researcher site file; and file the original in the participants' medical note.	

Please provide participant with SCIATiC– First Clinical Assessment Oswestry Disability Index Questionnaire

Has the participant moderate to high severity (≥30) on Oswestry Disability Index?

Yes ☐ No ☐

Completed by :.....Date:.....

Demographic Data:								
Date of Birth:		☐☐☐☐☐☐☐☐ (DD / MM / YYYY)						
Ethnicity:								
White	English	☐	Welsh	☐	Scottish	☐	Northern Irish	☐
	British	☐	Irish	☐	Gypsy or Irish traveller	☐	Other White background please describe below	☐
Comments:-								
Mixed / multiple ethnic groups	White & Black Caribbean	☐	White & Black African	☐	Other Mixed / Multiple ethnic background, please describe below		☐	
Comments:-								
Asian / Asian British	Indian	☐	Pakistani	☐	Bangladeshi		☐	
	Chinese	☐	Other Asian, please describe below				☐	
Comments:-								
Black / African / Caribbean / Black British	African	☐	Caribbean	☐	Other Black / African / Caribbean background, please describe below		☐	
Comments:-								
Other ethnic group	Arab	☐	Other ethnic group, please describe below				☐	
Comments:-								

Completed by :.....Date:.....

Sex: ☐ Male ☐ Female	
Height (cm): ☐☐☐	**Weight** (Kg): ☐☐.☐☐

Employment Status:

Employed – full time ☐ Employed – part time ☐

Self-employed ☐ Student ☐

House wife/husband ☐ Retired ☐

Unemployed ☐

Is the participant currently absent from work due to sciatica? Yes ☐ No ☐

Not applicable ☐

If **yes**, have they been:

Self-certified ☐ Certified sick by their doctor ☐

Other ☐ Please specify……..

Pain Assessment

Is the participant experiencing the following:-

Leg pain worse or as bad as back pain Yes ☐ No ☐

Unilateral leg pain approximating a dermatomal distribution Yes ☐ No ☐

Has the participant experienced their current episode for less than 22 weeks? Yes ☐ No ☐

How long have they being experiencing their current episode of sciatica?

☐☐☐ Weeks

Have they had a previous episode of sciatica in the last ☐ ☐

six months? Yes No

If they have had a previous episode have they been pain free

for at least one month before this current episode? Yes ☐ No ☐
N/A ☐

Completed by :.....Date:.....

How long is it since they had a whole month without any sciatica symptoms?

Less than three month ☐

Three to six months ☐

Seven to twelve months ☐

One to two years ☐

Three to five years ☐

Six to ten years ☐

More than ten years ☐

Eligible patients must have persistent sciatica for at least 4 weeks and less than 4 months

Completed by :.....Date:.....

FIRST CLINICAL ASSESSMENT MEDICAL HISTORY

Previous Medical History

	Please tick	Please tick
Has the participant had any relevant medical history?	**Yes***	**No**
	Complete below	
Cauda equina syndrome		
Malignancy		
Recent spinal fracture		
Serious Infection		
Disc prolapse		
Tuberculosis		
Transplanted organ		
Demyelinating disorder		
Cardiac failure		
Pregnant or possibly pregnant		
Lactating		
Previous lumbar spine surgery		
Widespread pain		
Use of biological agents within previous six months		

*If **YES** for any of the above, please give further details (including dates) and state if the condition is still active. If giving details of surgery please state the underlying cause. Use a separate line for each condition.

	Currently Active	
Details (Including Dates)	Yes	No

Completed by :.....Date:.....

FIRST CLINICAL ASSESSMENT PHYSICAL EXAMINATION

Code	Examination Finding	Please tick *Abnormal	Please tick Normal
1	Straight leg raise left		
2	Straight leg raise right		
3	Femoral stretch test left		
4	Femoral stretch test right		
5	Muscle power		
6	Pin prick sensation		
7	Tendon reflexes		

*If Abnormal enter the code below boxes and give brief details. Please use a separate line for each condition

Code	Details

Completed by :.....Date:.....

FIRST CLINICAL ASSESSMENT CONCOMITANT MEDICATIONS

Is the participant taken any concomitant medications at screening						☐ No ☐ Yes, Complete below		
Medication (Record Generic or trade name)	**Reason for use** (Medical History diagnosis or other reason, e.g. Prophylaxis)	Dose	units	**Frequency**	**Route**	**Start Date** (DD/MM/YYYY)	**Stop Date** (DD//MM/YYY)	**Or tick if ongoing at Screening Visit**
1.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
2.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
3.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
4.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
5.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
6.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
7.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
Please add additional concomitant medication logs as required						☐ **Please check box if this is the last page used**		

Completed by :.....Date:.....

FIRST CLINICAL ASSESSMENT INCLUSION/EXCLUSION CHECK

Part A: To be completed for all participants

Participants should only be entered into the SCIATiC study if the '**Yes**' box for each row under Inclusion Criteria has been ticked.

Inclusion criteria

Please check these inclusion criteria for the participant and tick the appropriate box for each row:

	YES	NO
Are they aged 18 years or older?		
Current leg pain worse than, or as bad as, back pain		
Unilateral leg pain approximating a dermatomal distribution (contralateral buttock pain permitted if it does not extend below the inferior gluteal margin)		
At least one of the following:- • Positive straight leg raise test (SLR) restricted <50 degrees by leg pain • Positive femoral stretch test • Muscle weakness in one myotome • Loss of tendon reflex • Loss of sensation in a dermatomal distribution		
Have they had persistent symptoms of the above for less than 22 weeks?		
Have they scored moderate to high severity (≥30) on the Oswestry Disability Index?		
Are they using a method of contraception? *(please note women who are pre-menopausal or not surgically sterile), must have a negative pregnancy test within two weeks of entering the trial)*		
Have they given informed consent?		

Completed by :.....Date:.....

Participants should only be entered into the SCIATiC study if the '**No**' box for each row under Exclusion Criteria has been ticked.

Exclusion criteria

Please check these exclusion criteria for the participant and tick the appropriate box for each row:

	YES	NO
Have their Sciatica symptoms persisted for longer than six months?		
Suspected serious spinal pathology, including cauda equina syndrome, malignancy, fracture or infection?		
Prior use of biological agents targeting TNF-alpha within the previous six months?		
Previous spinal surgery?		
Contra-indications to adalimumab injection including serious infection such as active or latent tuberculosis, transplanted organ, demyelinating disorders, malignancy, cardiac failure?		
Contra-indications to MRI including metal implants, potential metallic intra-ocular foreign bodies, claustrophobia?		
Pregnant, possibly pregnant or lactating?*		
Unable to communicate in English or Welsh?		

- Please ensure that response to pregnancy or possibly pregnant is the same as at the first assessment on page 9, if not please clarify with the participant

Is the participant eligible to take part in the study? Yes ☐ No ☐

If eligible to participate in the study please register the participant.

Completed by :.....Date:.....

If participant has consented to take part in the study please confirm the participant has been sent for the following:

Blood tests:	**Yes**	**No**	**Not applicable**
FBC	☐	☐	
U&E	☐	☐	
LFT	☐	☐	
Hba1c	☐	☐	
eGFR	☐	☐	
TB screening which may include CXR	☐	☐	
Biological agent counselling	☐	☐	
Pregnancy test	☐	☐	☐
MRI scan	☐	☐	

Completed by :.....Date:.....

SECOND CLINICAL ASSESSMENT

Date of Assessment:

DD MM YYYY

Pain Assessment

Is the patient still experiencing the following?

Leg pain worse or as bad as back pain Yes ☐ No ☐

Unilateral leg pain approximating a dermatomal distribution Yes ☐ No ☐

Has the participant experienced their current episode of sciatica for more than four weeks? Yes ☐ No ☐

Has the participant experienced their current episode of sciatica for less than 26 weeks? Yes ☐ No ☐

Please provide participant with SCIATiC– Second Clinical Assessment Oswestry Disability Index Questionnaire

Has the participant moderate to high severity (≥30) on Oswestry Disability Index?

Yes ☐ No ☐

Completed by :.....Date:.....

Lab Analysis:

Sample Required	**Date Sample Taken (DD/MM/YYYY**
Full Blood Count	☐☐ ☐☐ ☐☐☐☐
Liver Function Test	☐☐ ☐☐ ☐☐☐☐
Urea and Electrolytes	☐☐ ☐☐ ☐☐☐☐
HbA1C	☐☐ ☐☐ ☐☐☐☐
eGFR	☐☐ ☐☐ ☐☐☐☐

Are all final results Normal ☐ Abnormal ☐

Please note if results are abnormal and clinically significant further discussion will be required with the rheumatologist.

Abnormal results after discussion with rheumatologist

Abnormal (Not Clinically Significant) ☐ **Abnormal (Clinically Significant) ☐

**Description:----------

Pregnancy test (if applicable):

Date: ☐☐ ☐☐ ☐☐☐☐

Positive ☐ Negative ☐

Not applicable ☐

Completed by :.....Date:.....

TB screening

Date: ☐☐ ☐☐ ☐☐☐☐

Positive ☐ Negative ☐

Biological counselling given:

Yes ☐ No ☐

Biological counselling given by: _____

Date of counselling: ☐☐ ☐☐ ☐☐☐☐

MRI scan

Date: ☐☐ ☐☐ ☐☐☐☐

Result- Serious Spinal Pathology Absent?

Yes ☐ No ☐

Does any results contradict study entry?

Yes* ☐ No ☐

If *Yes participant must not continue.

Completed by :.....Date:.....

Reconfirmation of Inclusion & Exclusion Criteria

Part A: To be completed for all patients

Participants should only be entered into the SCIATiC study if the '**Yes**' box for each row under Inclusion Criteria has been ticked.

Inclusion criteria

Please check these inclusion criteria for the participant and tick the appropriate box for each row:

	YES	NO
Are they aged 18 years or older?		
Current leg pain worse than, or as bad as, back pain?		
Unilateral leg pain approximating a dermatomal distribution (contralateral buttock pain permitted if it does not extend below the inferior gluteal margin)?		
One of the following:- • Positive straight leg raise test (SLR) restricted <50 degrees by leg pain • Positive femoral stretch test • Muscle weakness in one myotome • Loss of tendon reflex • Loss of sensation in a dermatomal distribution		
Have they had persistent symptoms of the above for at least four weeks and less than 26 weeks?		
Have they scored moderate to high severity (≥30) on the Oswestry Disability Index?		
Are they using a method of contraception? *(please note women who are pre-menopausal or not surgically sterile), must have a negative pregnancy test within two weeks of entering the trial)*		

Completed by :.....Date:.....

Participants should only be entered into the SCIATiC study if the '**No**' box for each row under Exclusion Criteria has been ticked.

Exclusion criteria

Please check these exclusion criteria for the participant and tick the appropriate box for each row:

	YES	NO
Have their symptoms persisted for longer than six months?		
Presence of serious spinal pathology, including cauda equina syndrome, malignancy, fracture or infection?		
Prior use of biological agents targeting TNF-alpha within the previous six months?		
Previous spinal surgery?		
Contra-indications to adalimumab injection including serious infection such as active or latent tuberculosis, transplanted organ, demyelinating disorders, malignancy, cardiac failure?		
Contra-indications to MRI including metal implants, potential metallic intra-ocular foreign bodies, claustrophobia?		
Pregnant, possibly pregnant or lactating?		
Unable to communicate in English or Welsh?		

Is the participant eligible to take part in the study?

Yes ☐ No ☐

If participant is eligible to participate in the study please give Patient Information Sheet and Informed Consent Form part two to patient

Completed by :.....Date:.....

Informed Consent:

Has the participant given informed consent?

Yes ☐ *** No** ☐

Date participant signed written consent form 2: ☐☐ ☐☐ ☐☐☐☐

DD / MM/ YYY

Name of person taking informed consent: _____

Please give a copy of the signed copy of the informed consent form to the participant; a copy for the researcher site file; and file the original in the participants' medical note.

If no, Participant unable to proceed further

Completed by :.....Date:.....

Part B: To be completed if participant is eligible to take part in the study

SECOND CLINICAL ASSESSMENT PARTICIPANT ELIGIBILITY REVIEW

Document	Completed	Reason for non-completion	Initials of researcher
Eligibility criteria			
Consent form 1			
1st Clinical assessment screening booklet			
Consent form 2			
2nd Clinical assessment screening booklet			
Baseline questionnaire booklet			

If participant has consented please confirm the following:

Participant's eligibility Investigator Sign-Off:	
Is the participant eligible to take part in the Clinical Trial? ☐☐ ☐☐ ☐☐☐☐ (DD / MM / YYYY)	☐Yes ☐No, Please give reason for screen failure below
Reason(s) for screen failure:	
1.	
2.	
3.	

If the participant decided not to consent, did they indicate the reason for this? (*It is not compulsory for the participant to answer this question)*

Burden on time ☐
Did not want to be randomised ☐
Did not want to be in a research study ☐
Did not want to answer questionnaires ☐
Other (*please specify)* ☐

Completed by :.....Date:.....

Participant Randomisation	
Date of Randomisation	☐☐ ☐☐ ☐☐☐☐ **(DD / MM / YYYY)**

Completed by :.....Date:.....

Date of Assessment:

☐☐ ☐☐ ☐☐☐☐

(DD/MM/YYYY)

FIRST TRIAL MEDICATION ADMINISTRATION

If treatment is not given on date of randomisation please ask participant the following:

		Yes	No
1.	**Have there been any new Adverse Events?** (If yes, please record in Adverse Events page)	☐	☐
2.	**Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log)	☐	☐

Details of who was present at time of first injection

Name **Job Title** **Signature** **Date(DD/MM/YYYY**

SCIATiC Trial Administration

Date of Dosing (DD/MM/YYYY)	**Dose**	**Units**	**Was the participants treatment dose :-**		
			Interrupted	**Yes** ☐	**No** ☐
			Dose checking	Batch Number	

Completed by :.....Date:.....

Was the 1st Injections given on same day as randomisation?

YES ☐ NO ☐

If no, please provide details:-

……

……

……

Which treatment does the participant consider they have received today?

1	Definitely in the 0.9% sodium chloride injection group	☐
2	More likely to be in the 0.9% sodium chloride injection group	☐
3	Equally likely to be in the 0.9% sodium chloride injection group or the adalimumab injection group	☐
4	More likely to be in the adalimumab injection group	☐
5	Definitely in the adalimumab injection group	☐

Arrange participant to attend physiotherapy intervention

Completed by :……Date:……

PHYSIOTHERAPY INTERVENTION COVER SHEET

Number of physiotherapy courses given to participant: ☐

Treatment start date: ☐☐ ☐☐ ☐☐☐☐

DD/MM/YYYY

Treatment Stop date: ☐☐ ☐☐ ☐☐☐☐

DD/MM/YYYY

Outcome of treatment:

Discharged back to GP care ☐

Referred to interface services ☐

Referred to spinal orthopaedics or neurosurgery ☐

Physiotherapy intervention form completed? Yes ☐ No ☐

If no, please provide details:-

……

……

Completed by :……Date:……

Date of Assessment:

☐☐ ☐☐ ☐☐☐☐

(DD/MM/YYYY)

SECOND TRIAL MEDICATION ADMINSTRATION

Date of Visit: ☐☐ ☐☐ ☐☐☐☐

(DD / MM / YYYY)

Visit Checklist:			
		Yes	**No**
1.	**Have there been any new Adverse Events?** (If yes, please record in Adverse Events page)	☐	☐
2.	**Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log)	☐	☐

Is the participant still able to receive the second injection?

Yes ☐ No ☐

If no please provide further details:

……

……

Is the participant eligible to continue?

Yes ☐ No ☐

Completed by :……Date:……

Prior to the patient receiving their second injection please ask which treatment does the participant consider they have received today?

1	Definitely in the 0.9% sodium chloride injection group	☐
2	More likely to be in the 0.9% sodium chloride injection group	☐
3	Equally likely to be in the 0.9% sodium chloride injection group or the adalimumab injection group	☐
4	More likely to be in the adalimumab injection group	☐
5	Definitely in the adalimumab injection group	☐

Details of who was present at time of second injection

Name **Job title** **Signature** **Date**

SCIATiC Trial Administration

<table>
<tr><th>Date of Dosing
(DD/MM/YYYY)</th><th>Dose</th><th>Units</th><th colspan="3">Was the participants treatment dose :-</th></tr>
<tr><td rowspan="3">☐☐ ☐☐ ☐☐☐☐</td><td rowspan="3"></td><td rowspan="3"></td><td>Delayed</td><td>Yes ☐</td><td>No ☐</td></tr>
<tr><td>Interrupted</td><td>Yes ☐</td><td>No ☐</td></tr>
<tr><td colspan="2">Dose checking</td><td>Batch Number</td></tr>
</table>

Completed by :.....Date:.....

Post second injection please ask which treatment does the participant consider they have received today?

1	Definitely in the 0.9% sodium chloride injection group	☐
2	More likely to be in the 0.9% sodium chloride injection group	☐
3	Equally likely to be in the 0.9% sodium chloride injection group or the adalimumab injection group	☐
4	More likely to be in the adalimumab injection group	☐
5	Definitely in the adalimumab injection group	☐

Completed by :.....Date:.....

ADVERSE EVENTS PAGE

Part A **(to be completed by Researcher, Research nurse or Principal Investigator at the treatment site.)**

SCIATiC Trial Adverse Event Report	
Date of report	_ _/_ _/ _ _ _ _
Details of adverse event	
Comments (if applicable) **Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log) Onset (dd/mm/yyyy)	_ _/_ _/ _ _ _ _
Severity	Mild ☐ Moderate ☐ Severe ☐
Relationship to SCIATiC treatment	Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely ☐
Expectedness	Expected ☐ Unexpected ☐
AE outcome	Resolved ☐ Resolved with sequaelae ☐ Persisting ☐ Death ☐ Unknown ☐
Resolution date (dd/mm/yyyy)	_ _/_ _/ _ _ _ _
Reported as serious?	YES ☐ NO ☐

If adverse event is deemed as serious PI to complete part B

Completed by :.....Date:.....

Part B (to be completed by Principal Investigator)

Action Taken as Result of Serious Adverse Event:	
☐ None	*Give detail, including new dose (units), date(s) of administration and duration:*
☐ Dose changed	
☐ Medication interrupted	
☐ Medication discontinued	
☐ Other *(i.e. Treated with concomitant medication(s))*	*Tick if **concomitant medication** is listed on a separate sheet and indicate number of pages*
☐ Unknown at time of report	☐ **Pages:**

Blinding Information			
Blind Broken:	☐ *No*	☐ *Yes*	☐ *Not Applicable*
Is the information on this form likely to un-blind the reviewer			
☐ *No*		☐ *Yes*	
if Yes send to unblinded reviewer			
☐ Continuing in the trial			
☐ Completed the trial	**Date of Completion:**	_ _/_ _/ _ _ _ _	
☐ Withdrawn from the trial	**Date of Withdrawal:**	_ _/_ _/ _ _ _ _	

Name of PI

Signature of PI

Date of signature _ _/_ _/ _ _ _ _

PI Confirmation - This form is completed satisfactorily ☐*Yes* ☐*No*

Part C (to be completed by Chief Investigator/ delegated reviewer)

Was SAE drug related ☐ *Yes* ☐ *No*

SAE event No ☐☐☐☐☐☐☐/☐☐

Was the event unexpected ☐ *Yes* ☐ *No*

Was the event a SUSAR ☐ *Yes* ☐ *No*

Comments

Name of reviewer

Signature of reviewer

Date of signature

_ _/_ _/_ _ _ _

Date sent to MHRA

(SUSAR only) _ _/_ _/_ _ _ _

CONCOMITANT MEDICATIONS LOG

Has the participant used any Concomitant Medications?						☐ **No** ☐ **Yes,** Complete below		
Medication (Record Generic or trade name)	**Reason for use** (Medical History diagnosis or other reason, e.g. Prophylaxis)	Dose	units	**Frequency**	**Route**	**Start Date** (DD/MM/YYYY)	**Stop Date** (DD//MM/YYY)	**Or tick if ongoing**
1.						☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐	☐
2.						☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐	☐
3.						☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐	☐
4.						☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐	☐
5.						☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐	☐
6.						☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐	☐

Please add additional concomitant medication logs as required ☐ **Please check box if this is the last page used**

Note: Use the Concomitant log to record Non-IMPs

Completed by :.....Date:.....

WITHDRAWAL FORM

Please return to: SCIATiC trial manager NWORTH, Bangor University, Normal Site, Meirion Building, Holyhead Road, Bangor LL57 2DG

Centre Name: .....

If the SCIATiC participant can/will no longer fully comply with the SCIATiC protocol, please indicate the level that they wish to withdraw below:

1.	Patient does not wish to participate in further SCIATiC trial treatment but gives consent for data regarding their health status to be collected	☐	0=No 1=Yes
2	Patient does not wish to participate in any aspect of the SCIATiC trial and withdraws consent for any data to be collected regarding their health status	☐	0=No 1=Yes
3	Patient would like to give their reason(s) for withdrawing (this is completely optional).	☐	0=No 1=Yes

If question 3 has been answered "Yes", please write the participant's reasons below, or attach a separate sheet.

I confirm that the information provided above is correct to the best of my knowledge, and that I have taken a copy for the participants file.

Signed by (authorised person) .....

Print name.....

Date of completion ..... / ..... / .....

TRIAL COMPLETION

Date finished study: ☐☐ ☐☐ ☐☐☐☐

DD/MM/YYY

Date last study medication given: ☐☐ ☐☐ ☐☐☐☐

DD/MM/YYYY

REASON FINISHED STUDY

Please only mark the primary reason. All reasons other than 'COMPLETED STUDY' require an explanation next to the response.

☐ Completed study

☐ AE/SAE (complete AE CRF and SAE form if applicable)

☐ Lost to follow-up

☐ Non-compliant participant

☐ Concomitant medication

☐ Medical Contraindication

☐ Consent withdrawn –*if withdrawn please complete withdrawal form*

☐ Death (complete SAE form)

☐ Other *(specify*……..

……

……

Principal Investigator's Sign Off

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

Centre Name: _____

Principal Investigator's Name:
(Please print name): _____

Principal Investigator's Signature: _____

Date: ☐☐ ☐☐ ☐☐☐☐
(DD/MM/YYYY)

ONCE SIGNED NO FURTHER CHANGES CAN BE MADE TO THIS CRF WITHOUT AUTHORISATION.

Sub**C**utaneous

Injection of

Adalimumab

Tr**i**al Compared with

Control

S.7 PHYSIOTHERAPY INTERVENTION FORM

Please keep this form attached to physiotherapy notes. On discharge this must be sent to (*please provide details of local SCIATiC trial co-ordinator) for upload to MACRO system.*

Participant ID number ☐☐☐☐☐☐☐	Name of Physiotherapist: Treatment Site:

General summary of patient's problem and diagnosis/clinical impression:

Location of pain

Neural Tension Test:

Neurological deficit:

Oswestry Disability Score:

Comments:

Dates Participants Did Not Attend: ……./……./……., ……./……./……., ……./……./……., Total Number: ☐	Total Visits: ☐
Dates Participants Could not attend: ……./……./……., ……./……./……., ……./……./……., Total Number: ☐	Duration of treatment (weeks) ☐

Date attended	Did the participant experience an AE or SAE? Yes ☐ No ☐ If yes please provide details of event to research physiotherapist, with start and stop dates and treatment given: *(ensure an AE/SAE form in the CRF is completed)* Any changes to Conmeds? Yes ☐ No ☐ If yes please provide details to research physiotherapist to update conmed sheet	.. / .. / ..	Did the participant experience an AE or SAE? Yes ☐ No ☐ If yes please provide details of event to research physiotherapist, with start and stop dates and treatment given: *(ensure an AE/SAE form in the CRF is completed)* Any changes to Conmeds? Yes ☐ No ☐ If yes please provide details to research physiotherapist to update conmed sheet	.. / .. / ..	Did the participant experience an AE or SAE? Yes ☐ No ☐ If yes please provide details of event to research physiotherapist, with start and stop dates and treatment given: *(ensure an AE/SAE form in the CRF is completed)* Any changes to Conmeds? Yes ☐ No ☐ If yes please provide details to research physiotherapist to update conmed sheet	.. / .. / ..

Modalities Used (please tick ✓)	Date	✓	Date	✓	Date	✓
Advice & education & reassurance						
Medication usage discuss/review						
Specific exercise: Stability						
Specific exercise: McKenzie						
Specific exercise: Neural glides						
Specific exercise: Other						
Joint mobilisations/ manipulations						
Soft tissue techniques						
Other treatment (give details)						
Action plan for relapse discussed						

Outcome e.g. onwards referral or discharge		
	Discharged back to GP care	☐
	Referred to interface services	☐
	Referred to spinal orthopaedics or neurosurgery	☐

Any comments:

Date attended	Did the participant experience an AE or SAE? Yes ☐ No ☐ If yes please provide details of event to research physiotherapist, with start and stop dates and treatment given: *(ensure an AE/SAE form in the CRF is completed)* Any changes to Conmeds? Yes ☐ No ☐ If yes please provide details to research physiotherapist to update conmed sheet	.. / .. / ..	Did the participant experience an AE or SAE? Yes ☐ No ☐ If yes please provide details of event to research physiotherapist, with start and stop dates and treatment given: *(ensure an AE/SAE form in the CRF is completed)* Any changes to Conmeds? Yes ☐ No ☐ If yes please provide details to research physiotherapist to update conmed sheet	.. / .. / ..	Did the participant experience an AE or SAE? Yes ☐ No ☐ If yes please provide details of event to research physiotherapist, with start and stop dates and treatment given: *(ensure an AE/SAE form in the CRF is completed)* Any changes to Conmeds? Yes ☐ No ☐ If yes please provide details to research physiotherapist to update conmed sheet	.. / .. / ..

Modalities Used (please tick ✓)	Date	✓	Date	✓	Date	✓
Advice & education & reassurance						
Medication usage discuss/review						
Specific exercise: Stability						
Specific exercise: McKenzie						
Specific exercise: Neural glides						
Specific exercise: Other						
Joint mobilisations/ manipulations						
Soft tissue techniques						
Other treatment (give details)						

Action plan for relapse discussed	
Outcome e.g. onwards referral or discharge	Discharged back to GP care ☐ Referred to interface services ☐ Referred to spinal orthopaedics or neurosurgery ☐
Any comments:	

Has the participant used any Concomitant Medications?						☐ **No** ☐ **Yes,** Complete below		
Medication (Record Generic or trade name)	**Reason for use** (Medical History diagnosis or other reason, e.g. Prophylaxis)	Dose	units	**Frequency**	**Route**	**Start Date** (DD/MM/YYYY)	**Stop Date** (DD//MM/YYY)	**Or tick if ongoing**
1.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
2.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
3.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
4.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
5.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
6.						☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐
Please add additional concomitant medication logs as required						☐ **Please check box if this is the last page used**		

CONCOMITANT MEDICATIONS LOG

Note: Use the Concomitant log to record Non-IMPs

Completed by :.....Date:.....

ADVERSE EVENTS PAGE

Part A **(to be completed by Researcher, Research nurse or Principal Investigator at the treatment site.)**

SCIATiC Trial Adverse Event Report	
Date of report	_ _/_ _/ _ _ _ _
Details of adverse event	
Comments (if applicable) **Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log)	
Onset (dd/mm/yyyy)	_ _/_ _/ _ _ _ _
Severity	Mild ☐ Moderate ☐ Severe ☐
Relationship to SCIATiC treatment	Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely ☐
Expectedness	Expected ☐ Unexpected ☐
AE outcome	Resolved ☐ Resolved with sequaelae ☐ Persisting ☐ Death ☐ Unknown ☐
Resolution date (dd/mm/yyyy)	_ _/_ _/ _ _ _ _
Reported as serious?	YES ☐ NO ☐

If adverse event is deemed as serious PI to complete part B

Please add additional adverse event pages as required ☐

Please check box if this is the last page used

Participant Identification Number

SCIATiC

SubCutaneous Injection of Adalimumab Trial Compared with Control

[redacted]

This is an index used by clinicians and researchers to measure disability for low back pain. Please answer every section, and mark in each section only the ***one box*** which applies to you. We realise you may consider that two of the statements in any one section relate to you, but please ***just mark the box which most closely*** describes your problem.

Section 1 – Pain Intensity

I can tolerate the pain I have without having to use pain killers. ❑

The pain is bad but I manage without pain killers. ❑

Pain killers give complete relief from pain. ❑

Pain killers give moderate relief from pain. ❑

Pain killers give very little relief from pain. ❑

Pain killers have no effect on the pain and I do not use them. ❑

Section 2 – Personal Care (Washing, Dressing, etc)

I can look after myself normally without causing extra pain. ❑

I can look after myself normally but it causes extra pain. ❑

It is painful to look after myself and I am slow and careful. ❑

I need some help but manage most of my personal care. ❑

I need help every day in most aspects of self care. ❑

I do no get dressed, wash with difficulty and stay in bed. ❑

Section 3 - Lifting

I can lift heavy weights without extra pain. ❑

I can lift heavy weights but it gives extra pain. ❑

Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, eg on a table. ❑

Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned. ❑

I can lift only very light weights. ❑

I cannot lift or carry anything at all. ❑

Section 4 – Walking

Pain does not prevent me walking any distance. ❑

Pain prevents me walking more than 1 mile. ❑

Pain prevents me walking more than ½ mile. ❑

Pain prevents me walking more than ¼ mile. ❑

I can only walk using a stick or crutches. ❑

I am in bed most of the time and have to crawl to the toilet. ❑

Section 5 - Sitting

I can sit in any chair as long as I like. ❑

I can only sit in my favourite chair as long as I like. ❑

Pain prevents me sitting more than an hour. ❑

Pain prevents me from sitting more than ½ hour. ❑

Pain prevents me from sitting more than 10 mins. ❑

Pain prevents me from sitting at all. ❑

Section 6 – Standing

I can stand as long as I want without extra pain. ❑

I can stand as long as I want but it gives me extra pain. ❑

Pain prevents me from standing for more than 1 hour. ❑

Pain prevents me from standing for more than 30 mins. ❑

Pain prevents me from standing for more than 10 mins. ❑

Pain prevents me from standing at all. ❑

Section 7 – Sleeping

Pain does not prevent me from sleeping well. ❑

I can sleep well only by using tablets. ❑

Even when I take tablets I have less than six hours sleep. ❑

Even when I take tablets I have less than four hours sleep. ❑

Even when I take tablets I have less than two hours sleep. ❑

Pain prevents me from sleeping at all. ❑

Section 8 – Sex Life

My sex life is normal and causes no extra pain. ❑

My sex life I normal but causes some extra pain. ❑

My sex life is nearly normal but is very painful. ❑

My sex life is severely restricted by pain. ❑

My sex life is nearly absent because of pain. ❑

Pain prevents any sex life at all. ❑

Section 9 – Social Life

My social life is normal and gives me no extra pain. ❑

My social life is normal but increases the degree of pain. ❑

Pain has no significant effect on my social life apart from limiting my more energetic interests, eg dancing, etc. ❑

Pain has restricted my social life and I do not go out as often. ❑

Pain has restricted my social life to my home. ❑

I have no social life because of pain. ❑

Section 10 – Travelling

I can travel anywhere without extra pain. ❑

I can travel anywhere but it gives me extra pain. ❑

Pain is bad but I manage journeys over two hours. ❑

Pain restricts me to journeys of less than one hour. ❑

Pain restricts me to short necessary journeys under 30 min. ❑

Pain prevents me from travelling except to the doctors or hospital. ❑

Thank you for your time and co-operation in answering these questions.

Patient Identification Number: | | | | | | | |

SCIATiC

SubCutaneous Injection of Adalimumab Trial Compared with Control

Baseline Questionnaire

[redacted]

Participant Baseline Questionnaire Booklet

Thank you for participating in this research study. An important part of this study is the questionnaire booklet which has been designed to measure the effects of your illness and treatment.
The information you provide will be kept strictly confidential and used only for medical research.

Please note that your doctor, physiotherapist or nurse will not see the answers you give and, if you have specific symptoms or problems as indicated here, you may need to discuss these with your doctor, physiotherapist or nurse in person.
If you find any of the questions are irrelevant or difficult please make a note of this on the last page.

Please answer all the questions yourself by entering your responses that best applies to you, as instructed.

There are no “right” or “wrong” answers.

Please enter the date on which you completed this questionnaire: ...../...../.....

Pain trajectory

How long is it since they had a whole month without any sciatica symptoms?

- Less than three month ☐
- Three to six months ☐
- Seven to twelve months ☐
- One to two years ☐
- Three to five years ☐
- Six to ten years ☐
- More than ten years ☐

Health Questionnaire

English version for the UK

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

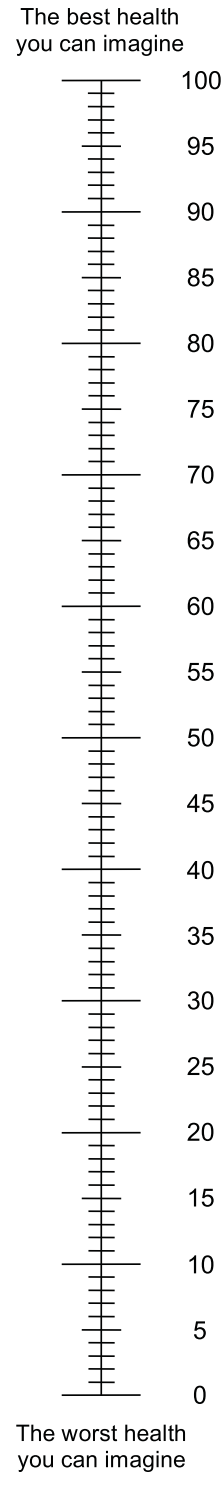
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Holiadur Iechyd

Fersiwn Cymraeg ar gyfer y Deyrnas Unedig

(Welsh version for Wales)

O dan bob pennawd, ticiwch yr UN blwch sy'n disgrifio eich iechyd chi HEDDIW orau.

SYMUDEDD

Dydw i ddim yn cael anhawster wrth gerdded o gwmpas ❑

Rydw i'n cael ychydig o anhawster wrth gerdded o gwmpas ❑

Rydw i'n cael anhawster cymedrol wrth gerdded o gwmpas ❑

Rydw i'n cael anhawster difrifol wrth gerdded o gwmpas ❑

Dydw i ddim yn gallu cerdded o gwmpas ❑

HUNAN-OFAL

Dydw i ddim yn cael anhawster ymolchi neu wisgo amdanaf ❑

Rydw i'n cael ychydig o anhawster ymolchi neu wisgo amdanaf ❑

Rydw i'n cael anhawster cymedrol ymolchi neu wisgo amdanaf ❑

Rydw i'n cael anhawster difrifol ymolchi neu wisgo amdanaf ❑

Dydw i ddim yn gallu ymolchi neu wisgo amdanaf ❑

GWEITHGAREDDAU ARFEROL *(e.e. gwaith, astudio, gwaith tŷ, gweithgareddau teuluol neu hamdden)*

Dydw i ddim yn cael anhawster gwneud fy ngweithgareddau arferol ❑

Rydw i'n cael ychydig o anhawster gwneud fy ngweithgareddau arferol ❑

Rydw i'n cael anhawster cymedrol gwneud fy ngweithgareddau arferol ❑

Rydw i'n cael anhawster difrifol gwneud fy ngweithgareddau arferol ❑

Dydw i ddim yn gallu gwneud fy ngweithgareddau arferol ❑

POEN / ANGHYSUR *(e.e. teimlo'n anghyfforddus)*

Does gen i ddim poen nac anghysur ❑

Mae gen i ychydig o boen neu anghysur ❑

Mae gen i boen neu anghysur cymedrol ❑

Mae gen i boen neu anghysur difrifol ❑

Mae gen i boen neu anghysur eithafol ❑

PRYDER / ISELDER

Dydw i ddim yn teimlo'n bryderus nac yn isel ❑

Rydw i'n teimlo ychydig yn bryderus neu isel ❑

Rydw i'n teimlo'n gymedrol o bryderus neu isel ❑

Rydw i'n teimlo'n ddifrifol o bryderus neu isel ❑

Rydw i'n teimlo'n eithafol o bryderus neu isel ❑

- Hoffem gael gwybod pa mor dda neu wael yw eich iechyd chi HEDDIW.
- Mae'r raddfa hon wedi ei rhifo o 0 i 100.
- Mae 100 yn golygu'r iechyd gorau y gallwch ei ddychmygu.
  Mae 0 yn golygu'r iechyd gwaethaf y gallwch ei ddychmygu.
- Rhowch X ar y raddfa i ddangos sut mae eich iechyd chi HEDDIW.
- Yn awr ysgrifennwch y rhif wnaethoch chi ei nodi ar y raddfa yn y blwch isod.

EICH IECHYD CHI HEDDIW = ☐