THE PEGASUS TRIAL

Patient Information Leaflet

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

We would like to invite you to take part in our research study. Before you decide if you want to take part we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information leaflet with you and answer any questions you have. We’d suggest this should take about 30 minutes. Please ask us if anything is unclear or if you would like more information. Taking part is voluntary and it is up to you to decide if you would like to take part.

Part (1) tells you the purpose of this study and what will happen to you if you take part. Part (2) gives you more detailed information about the conduct of the study.

**Part One**

**What is the purpose of the study?**

The most common complication following burns reported in up to 70% of patients, is red and raised (hypertrophic) scarring. This study is designed to look at the use of pressure garment therapy in the prevention of hypertrophic scarring. Scarring occurs when the burn wounds are healed and can vary with age, race, genetic factors, burn type and depth. Some people’s scars remain flat and supple and others become lumpy and firm.

Currently a selection of scar treatments are used throughout the UK and the world, with each treatment claiming to be the most effective. Unfortunately due to the lack of research and evidence not one particular treatment can be described as being ‘the best’.

The following treatments claim to be the most effective:

- Pressure Garment Therapy
- Moisturisation (moisturising creams and sun protection creams)
- Silicone (gels, creams, sheets and sprays)
- Massage

Pressure garments are bespoke Lycra® garments measured for and fitted by your scar management team and are recommended to be worn for 23 hours a day for up to 18 months.

Your involvement will help us see whether or not, in the future we will be able to conduct a larger study to look at the whether using pressure garments with massage, moisturisation and silicone helps to flatten and soften burns scars or if using massage, moisturisation and silicone, without pressure garment therapy is just as effective.
Examples of Pressure garments:

Why have I been invited?

You have been asked to join our study because:
1. You have sustained a burn injury greater than 1% of your total body surface area (TBSA)
2. You are eligible for scar management therapy intervention.

The trial will be carried out across six specialist burns units throughout the UK. Some centres specialise in treating adults or children, whereas others treat both adults and children.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information leaflet. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

Participation in this study is voluntary. If you decide that you would like to take part, a member of the study team, will explain the study to you and answer any questions you might have. They will ask you some questions about your health and any medication you may be taking. You will then be asked to sign a consent form. You should only do this if you are happy that you understand the project and want to take part.

If you consent to participate you will be randomly allocated to either:
- Pressure garment therapy with massage, moisturisation and silicone or;
- Massage, moisturisation and silicone

This means that there is a 50:50 chance (the same as tossing a coin) that you may or may not be allocated to wear pressure garments.

Patients will be closely monitored at months one, three, six, nine and 12 over a 12 month period. The 12 month appointment will only be completed if this date is before September 2015 as analysis of the trial’s data will begin at this point.

At each visit (approx. 2 hours) assessments may include:
- Range of motion
- Measurement of your scar’s elasticity
TO BE PRINTED ON LOCAL TRUST HEADED PAPER

- Photographs of your scar
- Completion of questionnaires

If you agree to take part in the trial, your hospital visits will be at the times when you would normally have hospital visits for your burn injury.

**Expenses and Payments**
You will not receive any expenses or payments for being involved in the study or for attending the outpatient appointments. There will be no additional hospital visits to make for the trial and all hospital visits will be at times when you would normally have appointments for your burn injury, as such, there will be no provision for travel expenses. Participants are not expected to pay for any treatments during the course of the trial.

**What will I have to do?**
The most important part of the study is attending all of the appointments and to comply with your therapy treatment plan i.e. massage, moisturisation, silicone and pressure garments (the latter, if applicable).

**What alternative treatments are available?**
Currently pressure garment therapy is just one of a range of treatments used in scar management. At the moment we do not know whether it is the pressure garment therapy or a combination of massage, moisturising cream and silicone that are useful in preventing hypertrophic scars.

**What are the possible disadvantages and risks of taking part?**
There are no associated risks with being involved in the study as all the procedures we are planning to perform are frequently performed in the hospital. In a small number of patients a rash may develop following the use of pressure garments and/or silicone. If this happens please inform your therapist and your treatment will be reviewed.

**What are the possible benefits of taking part?**
We are unable to guarantee any direct benefit to participants that take part in this trial. Nonetheless, you will be contributing to an improved understanding of scar management therapy. The information gained from this trial will also contribute to further studies and may help improve the treatment of people with a burn injury in the future.

**Part Two**

**What if relevant new information becomes available?**
Sometimes we get new information about the treatment being studied. We will tell you and your doctor about it and give you an opportunity to discuss it with a trial nurse or doctor. If this new information means that we should stop the study, or change how we are running it, we will do this and make sure that you are offered the best treatment.

**What will happen if I don’t want to carry on with the study?**
You are free to withdraw from the study at any time and this will not affect your care. You can either withdraw completely or choose to keep in contact with us to let us know your progress. Information collected earlier in the study may still be used.
What if there is a problem?
If you have concerns about any aspect of this study, you should ask to speak to the research coordinator who will do their best to answer your questions (contact numbers below).

We do not anticipate that anything will go wrong. We will of course take great care that nothing goes wrong but if you are harmed by taking part in this research you should understand that there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you: ask to speak to the complaints manager of the hospital.

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions (insert Local PI contact details here). If you remain unhappy and wish to complain formally you can contact your local Patient Advice and Liaison Services (PALS) group or local equivalent group (insert name where applicable) (insert contact details here).

Quality of life assessment
It is very important for us to understand the effect of your scar(s) and treatment on your quality of life so that we can provide future patients with information on what they can expect to experience.

You will therefore be asked to complete a questionnaire about your general well-being (EQ-5D questionnaire). We estimate that it will take around 10 minutes to complete the questionnaire.

Because only you truly know how you feel, we would like you to complete the questionnaire without input from family, loved ones or your clinical team. It is important to note that the data will be anonymised – no-one outside the research team will be able to identify your personal responses. The information you provide will be managed by the research team and summarised in reports at the end of the study.

This information will not be used to inform your clinical care directly; therefore, it is important that you let your clinical team (GP, nurse or hospital consultant) know if you have any concerns regarding your-wellbeing. Support can also be found from: [Please add appropriate support info e.g. PALS]

Will my taking part in this study be kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence. If you agree to take part, your doctor will send basic information about you and your condition to the PEGASUS Trial Office at the University of Birmingham Clinical Trials Unit (BCTU), on paper and electronically, where it will be securely stored under the provisions of the Data Protection Act 1998 and/or applicable laws and regulations. Information held by the NHS may be used to follow your progress. The study data may also be looked at by representatives of regulatory authorities and by other authorised people to check that the study is being carried out correctly. Your GP, and other doctors involved in your clinical care, will be kept informed. All those associated with the study will have a duty of confidentiality to you as a research participant.
TO BE PRINTED ON LOCAL TRUST HEADED PAPER

In line with Good Clinical Practice Regulations, at the end of the study, the data will need to be securely archived for at least 5 years (but ideally not less than 25 years). Arrangements for confidential destruction will then be made.

Involvement of the General Practitioner/Family Doctor (GP)
You will be asked to give permission for us to tell your GP on your behalf.

What will happen to the results of the research study?
The results will be published in medical journals or presented at medical conferences. All the information we present will continue to be anonymous. If you wish to be informed of the results of the study, please inform the research staff and we can ensure that this happens at the end of the study once all the information has been analysed.

Who is organising and funding the research?
The study is being coordinated by the University of Birmingham Clinical Trials Unit and is funded by the National Health Research’s Health Technology Assessment Programme (project number 12/145/04).

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands Ethics Committee.

Further information and contact details
If you require any further information please contact the research team on the details below. If you would prefer to speak to an independent person, regarding the trial please contact the Patients Advice and Liaison Service (PALS) on xxx xxx xxxx

Contact Details for research team:

Principal Investigator

Research Nurse

Scar Management Therapist
# THE PEGASUS TRIAL
## Adult Consent Form

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

<table>
<thead>
<tr>
<th>Patient Identification Number:</th>
<th>(This number should be added by site staff immediately after randomisation)</th>
</tr>
</thead>
</table>

Please initial each box to confirm consent or leave blank

<table>
<thead>
<tr>
<th>I confirm that I have read and understood the Participant Information Leaflet dated</th>
<th>Initial here ↓</th>
</tr>
</thead>
<tbody>
<tr>
<td>(This number should be added by site staff immediately after randomisation)</td>
<td></td>
</tr>
</tbody>
</table>

| I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used. |               |

| I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. |               |

| I understand that my doctor will provide a copy of this consent form and personal information about my progress, in confidence, to the central organisers at Birmingham Clinical Trials Unit (BCTU) for use in the PEGASUS Trial. |               |

| I agree to my GP being informed of my participation in the PEGASUS Trial. |               |

| I understand that the information held and maintained by The Health and Social Care Information Centre and other central UK NHS bodies may be used to help contact me or provide information about my health status. To do this, I understand that my name, postcode and date of birth will be shared with these central bodies. |               |

| I agree to participate in the PEGASUS Trial |               |

<table>
<thead>
<tr>
<th>Name of participant</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of person taking consent</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 copy for the participant, original for the Investigator Site File, 1 copy to be retained in the hospital notes and 1 faxed to BCTU
THE PEGASUS TRIAL
Optional Consent Form – Future Research

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

Patient Identification Number: 
(This number should be added by site staff immediately after randomisation)

Please initial box to confirm consent or leave blank

I agree to being contacted in the future about other possible research trials.

Name of participant  Date  Signature

Name of person taking consent  Date  Signature

1 copy for the participant, original for the Investigator Site File, 1 copy to be retained in the hospital notes and 1 faxed to BCTU
THE PEGASUS TRIAL
Assent Form for Children and Young Adults

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

Patient Identification Number:  
(This number should be added by site staff immediately after randomisation)

Please read all of the questions below and tick the box if you are happy to answer yes to them. You can ask for help with this too if you like.

Remember it’s completely up to you if you take part and it will not affect your treatment if you choose not to.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you read (or had read to you) all of the information about this project?</td>
<td></td>
</tr>
<tr>
<td>Has someone else explained this project to you?</td>
<td></td>
</tr>
<tr>
<td>Do you understand what this project is about?</td>
<td></td>
</tr>
<tr>
<td>Have you asked all of the questions you want to?</td>
<td></td>
</tr>
<tr>
<td>Have you had your questions answered in a way that you understand?</td>
<td></td>
</tr>
<tr>
<td>Do you understand that it is okay to stop taking part at any time?</td>
<td></td>
</tr>
<tr>
<td>Would you like to take part in the PEGASUS Trial?</td>
<td></td>
</tr>
</tbody>
</table>

If you **do** want to take part, you can write your name below. The Doctor who explained this project to you needs to sign their name too.

<table>
<thead>
<tr>
<th>Write your name in the box below</th>
<th>Date</th>
<th>Your signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of the Doctor who explained this study to you</th>
<th>Date</th>
<th>Doctor’s signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 copy for the participant, original for the Investigator Site File, 1 copy to be retained in the hospital notes and 1 faxed to BCTU
QUALITY OF LIFE ASSESSMENTS

Separate EQ-5D or PedsQL and/or CHU9D questionnaires must be completed at the beginning of each visit

IDENTIFYING DETAILS

Trial No.:  
Participant initials:  
Participant’s Gender:  Male  Female  
Date of birth:  
Height:  cm  Weight:  kg  
Participant self-declared ethnicity code:  (Please refer to coded list; Note 1 at the end of this document)

Hospital Name:  
Principal Investigator:  
Date of visit:  

FITZPATRICK SCALE

The Fitzpatrick Scale should be used to classify the patient’s complexion and tolerance of sunlight.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Please tick one option</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/a White always burn, never tans</td>
<td></td>
</tr>
<tr>
<td>1/b White freckles/ red hair/ Celtic origin</td>
<td></td>
</tr>
<tr>
<td>2 White always burn but tans with difficulty</td>
<td></td>
</tr>
<tr>
<td>3 White sometimes mildly burns, but tans</td>
<td></td>
</tr>
<tr>
<td>4 Moderate brown and very rarely burns, tan easily</td>
<td></td>
</tr>
<tr>
<td>5 Dark brown and very rarely burns, moderately pigmented, tan easily</td>
<td></td>
</tr>
<tr>
<td>6 Black and never burns, tan easily</td>
<td></td>
</tr>
</tbody>
</table>
# BURN INJURY CHARACTERISTICS

Please record here the specific characteristics of the injury.

<table>
<thead>
<tr>
<th>Date of burn injury:</th>
<th></th>
</tr>
</thead>
</table>

Please specify the burn injury aetiology:

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal flame</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal flash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal scald</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal radiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical (low voltage, high voltage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical (acid, alkali)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Were any other injuries obtained at the same time as the burn injury?  
No [ ] Yes [ ]

If yes, please tick any other injuries that were obtained below:

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fractures/ sprains</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify opposite)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal injury</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### MEDICAL HISTORY

Please tick below if the patient has any significant co-morbidities.

<table>
<thead>
<tr>
<th>Category</th>
<th>Condition</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Neurological</strong></td>
<td>Cerebrovascular disease e.g. stroke or TIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dementia</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Previous traumatic brain injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hemiplegia or paraplegia</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cerebral palsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Epilepsy or Seizure disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Demyelinating Diseases (e.g. Multiple Sclerosis, Transverse Myelitis, Acute Disseminated Encephalomyelitis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Psychiatric/ behavioural</strong></td>
<td>Depressive disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Schizophrenia and other psychotic disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Delirium, dementia, and amnestic and other cognitive disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Eating disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attention-deficit and disruptive behavior Disorders (e.g. ADHD)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Mood disorders</td>
<td></td>
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<tr>
<td></td>
<td>Bipolar disorders</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Pervasive developmental disorders (e.g. Autism, Asperger’s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anxiety disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Musculoskeletal</strong></td>
<td>Rheumatoid arthritis</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Osteoarthritis</td>
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<tr>
<td></td>
<td>Gout</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Juvenile idiopathic arthritis</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dermatology</strong></td>
<td>Eczema</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Psoriasis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PEGASUS BASELINE ASSESSMENTS**

Version 1.3, 25\(^{th}\) March 2015

Page 3 of 14
<table>
<thead>
<tr>
<th>Category</th>
<th>Condition</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrinology</td>
<td>Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>Oedema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient smoke?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**VANCOUVER SCAR SCALE**

Using the Body Map mark and label the burn areas. The burns marked and labelled will be followed throughout the trial. A scar assessment using the adapted Vancouver Scar Scale below should then be completed for each of the burn sites. Please circle the most appropriate number in each one of the columns.

**Burn site number 1**
Continuation forms should be used for those patients that have more than one scar site.

<table>
<thead>
<tr>
<th>Pigmentation</th>
<th>Pliability</th>
<th>Height</th>
<th>Vascularity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Normal</td>
<td>0 Normal</td>
<td>0 Flat</td>
<td>0 Normal</td>
</tr>
<tr>
<td>1 Hypopigmented</td>
<td>1 Supple</td>
<td>1 &lt;2mm</td>
<td>1 Pink</td>
</tr>
<tr>
<td>2 Mixed</td>
<td>2 Yielding</td>
<td>2 2–5mm</td>
<td>2 Red</td>
</tr>
<tr>
<td>3 Hyperpigmented</td>
<td>3 Firm</td>
<td>3 &gt;5mm</td>
<td>3 Purple</td>
</tr>
<tr>
<td></td>
<td>4 Ropes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 Contracture</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
THE PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS)

Observer scale

**Burn site number 1**
Continuation forms should be used for those patients that have more than one scar site.

---

**1 = Normal Skin**

**10 = Worst Scar Imaginable**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascularity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>PALE</td>
</tr>
<tr>
<td>Pigmentation</td>
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<td></td>
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<td></td>
<td>HYPO</td>
</tr>
<tr>
<td>Thickness</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>THICKER</td>
</tr>
<tr>
<td>Relief</td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td>MORE</td>
</tr>
<tr>
<td>Pliability</td>
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<td></td>
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<td></td>
<td></td>
<td>SUPPLE</td>
</tr>
<tr>
<td>Surface Area</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EXPANSION</td>
</tr>
<tr>
<td>Overall Opinion</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Patient scale, to be completed only for adult patients (≥ 16 years old)

**Burn site number 1**
Continuation forms should be used for those patients that have more than one scar site.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the scar been painful the past few weeks?</td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Has the scar been itching the past few weeks?</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Is the scar colour different from the colour of your normal skin at present?</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the stiffness of the scar different from your normal skin at present?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the thickness of the scar different from your normal skin at present?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the scar more irregular than your normal skin at present?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is your overall opinion of the scar compared to normal skin?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 = no, not at all
10 = yes, very different

1 = no, as normal skin
10 = very different
PAEDIATRIC PAIN AND ITCH SCALES

Pain and itch scales are to be completed by paediatric patients who cannot complete the POSAS Patient Scale.

Paediatric Itch Scales
Please ask the patient to complete the scale most appropriate for their age and/or level of understanding. NB: Only one of the itch assessment scales below needs to be completed.

<table>
<thead>
<tr>
<th>Pain level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Comfortable, no itch</td>
</tr>
<tr>
<td>1</td>
<td>Itches a little; does not interfere with activity</td>
</tr>
<tr>
<td>2</td>
<td>Itches more; sometimes interferes with activity</td>
</tr>
<tr>
<td>3</td>
<td>Itches a lot; difficult to be still, concentrate</td>
</tr>
<tr>
<td>4</td>
<td>Itches most terribly; impossible to sit still, concentrate</td>
</tr>
</tbody>
</table>

If these assessments cannot be completed please tick here: ☐

Paediatric Itch Scale – Younger Patients. Please circle the most appropriate number.

Paediatric Itch Scale – Older Patients. Please mark level of itch as appropriate.
**Paediatric Pain Scales**
Please ask the patient to complete the scale most appropriate for their age and/or level of understanding. NB: Only one of the pain assessment scales below needs to be completed.

**Paediatric Pain Scale – Younger Patients. Please circle the most appropriate number.**

![Paediatric Pain Scale Image]

**Paediatric Pain Scale – Older Patients. Please mark level of pain as appropriate.**

![Paediatric Pain Scale Image]

**RANGE OF MOVEMENT ASSESSMENTS**
Active ROM should be recorded in the following section. Please indicate whether ROM has been reduced and if so the percentage of movement recorded for each affected joint, if these measurements are done as standard.

**Hand and wrist**
If this assessment is not applicable please tick here: [ ]

Which hand/ wrist has been affected by the burn injury? Please indicate below.

Has the burn injury resulted in a reduced range of movement? No [ ] Yes [ ]

For all digits, please select ‘Yes’ if ROM test was done, and enter the % score. If the test was not done, or the digit was missing, please just tick ‘No’.

<table>
<thead>
<tr>
<th></th>
<th>LEFT</th>
<th></th>
<th></th>
<th></th>
<th>RIGHT</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td>ROM (%)</td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>ROM (%)</td>
<td></td>
</tr>
<tr>
<td>Thumb MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Thumb MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Thumb IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Thumb IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Index Finger MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Index Finger MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>
RANGE OF MOVEMENT ASSESSMENTS

Active ROM should be recorded in the following section. Please indicate whether ROM has been reduced and if so the percentage of movement recorded for each affected joint, if these measurements are done as standard.

Hand and wrist

<table>
<thead>
<tr>
<th>Joint Type</th>
<th>Study Side 1</th>
<th>Study Side 2</th>
<th>Normal Side 1</th>
<th>Normal Side 2</th>
<th>Study Side 1</th>
<th>Study Side 2</th>
<th>Normal Side 1</th>
<th>Normal Side 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Finger PIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Index Finger DIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Middle Finger MCPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Middle Finger PIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Middle Finger DIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Ring Finger MCPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Ring Finger PIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Ring Finger DIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Little Finger MCPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Little Finger PIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
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<tr>
<td>Little Finger DIPJ</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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</tr>
<tr>
<td>Wrist Flexion</td>
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<tr>
<td>Wrist Extension</td>
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<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
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<tr>
<td>Ulnar Deviation</td>
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<td>☐ ☐ ☐</td>
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<td>☐ ☐ ☐</td>
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<tr>
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<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐</td>
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<tr>
<td>Pronation</td>
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<td>☐ ☐ ☐</td>
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</tr>
</tbody>
</table>
### Lower Quadrant

If this assessment is not applicable please tick here: [ ]

Has the burn injury resulted in a reduced range of movement?  
No [ ] Yes [ ]

**For all joints, please select ‘Yes’ if ROM test was done, and enter the % score. If the test was not done, please just tick ‘No’.

<table>
<thead>
<tr>
<th>LEFT</th>
<th>No</th>
<th>Yes</th>
<th>ROM (%)</th>
<th>RIGHT</th>
<th>No</th>
<th>Yes</th>
<th>ROM (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip Flexion</td>
<td>[ ]</td>
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<td>[ ]</td>
<td>Hip Flexion</td>
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<tr>
<td>Hip Extension</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Hip Extension</td>
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<td>[ ]</td>
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<tr>
<td>Hip Abduction</td>
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<td>[ ]</td>
<td>Hip Abduction</td>
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<td>[ ]</td>
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<tr>
<td>Hip Lateral Rotation</td>
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<td>[ ]</td>
<td>Hip Lateral Rotation</td>
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<tr>
<td>Hip Medial Rotation</td>
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<td>[ ]</td>
<td>[ ]</td>
<td>Hip Medial Rotation</td>
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<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Knee Flexion</td>
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</tr>
<tr>
<td>Knee Extension</td>
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<td>[ ]</td>
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</tr>
<tr>
<td>Ankle Dorsiflexion</td>
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<td>Ankle Dorsiflexion</td>
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</tr>
<tr>
<td>Ankle Plantar Flexion</td>
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<td>Ankle Plantar Flexion</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Forefoot Inversion</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Forefoot Inversion</td>
<td>[ ]</td>
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<td>[ ]</td>
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<tr>
<td>Forefoot Eversion</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Forefoot Eversion</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Foot MTPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Foot MTPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Big Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Big Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Long Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Long Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Middle Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Middle Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Ring Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Ring Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Little Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Little Toe IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### Upper Limb

If this assessment is not applicable please tick here:  

---

Has the burn injury resulted in a reduced range of movement?  

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For all joints, please select ‘Yes’ if ROM test was done, and enter the % score. If the test was not done, please just tick ‘No’.

<table>
<thead>
<tr>
<th></th>
<th>LEFT</th>
<th></th>
<th>RIGHT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes ROM (%)</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Scapulo-thoracic Elevation</td>
<td></td>
<td></td>
<td></td>
<td>Hip Flexion</td>
</tr>
<tr>
<td>Scapulo-thoracic Depression</td>
<td></td>
<td></td>
<td></td>
<td>Hip Extension</td>
</tr>
<tr>
<td>Scapulo-thoracic Protraction</td>
<td></td>
<td></td>
<td></td>
<td>Hip Abduction</td>
</tr>
<tr>
<td>Scapulo-thoracic Retraction</td>
<td></td>
<td></td>
<td></td>
<td>Hip Lateral Rotation</td>
</tr>
<tr>
<td>Glenohumeral Flexion</td>
<td></td>
<td></td>
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<td>Hip Medial Rotation</td>
</tr>
<tr>
<td>Glenohumeral Extension</td>
<td></td>
<td></td>
<td></td>
<td>Knee Flexion</td>
</tr>
<tr>
<td>Glenohumeral Lateral Rotation</td>
<td></td>
<td></td>
<td></td>
<td>Glenohumeral Lateral Rotation</td>
</tr>
<tr>
<td>Glenohumeral Medial Rotation</td>
<td></td>
<td></td>
<td></td>
<td>Glenohumeral Medial Rotation</td>
</tr>
<tr>
<td>Glenohumeral Abduction</td>
<td></td>
<td></td>
<td></td>
<td>Glenohumeral Abduction</td>
</tr>
<tr>
<td>Glenohumeral Adduction</td>
<td></td>
<td></td>
<td></td>
<td>Glenohumeral Adduction</td>
</tr>
<tr>
<td>Elbow Flexion</td>
<td></td>
<td></td>
<td></td>
<td>Elbow Flexion</td>
</tr>
<tr>
<td>Elbow Extension</td>
<td></td>
<td></td>
<td></td>
<td>Elbow Extension</td>
</tr>
</tbody>
</table>
**PRESSURE GARMENT THERAPY**

To be completed only for those patients that have been randomised to the PGT arm of the trial.

Was the patient measured for their pressure garments?  
No ☐ Yes ☐

If yes, where will the pressure garments be made?  
In house ☐ Externally ☐

If the patient was measured for pressure garments, record for which scar site number(s). Scar site number(s) must be the same as those used on the previous Vancouver Scar Scale:

<table>
<thead>
<tr>
<th>Scar site</th>
<th>Was/ were Pressure Garment(s) fitted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>2</td>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>3</td>
<td>No ☐ Yes ☐</td>
</tr>
</tbody>
</table>

**MEDICATION REVIEW**

Has the participant started any new medications or stopped any existing medications in relation to their burn injury since the last visit?  
No ☐ Yes ☐

If yes, please answer all questions in the Medication Review section

Please indicate whether the patient is currently taking or has started or stopped any of the following medications:

<table>
<thead>
<tr>
<th>Topical analgesics for pain and itch relief</th>
<th>N/A</th>
<th>Continuing</th>
<th>Started</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild analgesics, e.g., paracetamol, aspirin, NSAIDs</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Moderate opioid analgesics, e.g., codeine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Opioid analgesics, e.g., morphine, fentanyl</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other analgesics, e.g., gabapentin, pregabalin</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Antihistamines, e.g., cetirizine, diphenhydramine, loratadine, chlorphenamine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Estimated time spent on consultation (please include the time actually spent on the consultation, the time spent writing up patient notes and/or referral letters/letters to the patients GP). Please do not include the time spent completing the study-specific CRF.

Estimated time spent on consultation:  

Profession of person performing the visit: 
- Consultant [ ]
- Nurse [ ]
- Other (please specify opposite) [ ]
- Occupational Therapist [ ]
- Physiotherapist [ ]

Name of person who has completed this form (please print): 
Signature of person who has completed this form:

Note 1: Ethnicity codes based on 2011 Census
- 31 White - English / Welsh / Scottish / Northern Irish / British
- 32 White - Irish
- 33 White - Gypsy or Irish Traveller
- 34 White - Any Other White background
- 35 Mixed / Multiple ethnic group - White and Black Caribbean
- 36 Mixed / Multiple ethnic group - White and Black African
- 37 Mixed / Multiple ethnic group - White and Asian
- 38 Mixed / Multiple ethnic group - Any Other Mixed / multiple ethnic background
- 39 Asian / Asian British – Indian
- 40 Asian / Asian British – Pakistani
- 41 Asian / Asian British – Bangladeshi
- 42 Asian / Asian British – Chinese
- 43 Asian / Asian British - Any other Asian background
- 44 Black / African / Caribbean / Black British – African
- 45 Black / African / Caribbean / Black British – Caribbean
- 46 Black / African / Caribbean / Black British – Any other Black / African / Caribbean background
- 47 Other ethnic group – Arab
- 48 Other ethnic group – Any other ethnic group
- 98 Any other
- 99 Not known/not provided
THE PEGASUS TRIAL
Patient Information Leaflet for Children 6-10 Years

We would like to ask you to take part in a research study. Before you decide if you want to join in, it’s important to understand why the research is being done and what it means for you. Talk about it with your family, friends, doctor or nurse if you want to.

Remember if there is anything that you’re not too sure about you can ask your doctor or nurse at any time!

What is research? Why is this project being done?
Research is a way we try to find out the answers to questions. The project will look at what happens to our bodies after we have a burn.

Why have I been asked to take part?
You have been asked if you would like to take part because you:

1. Have a burn.
   and

2. Can wear a special bandage made for people who have had a burn called a pressure garment.

Did anyone else check the study is OK to do?
Before any research is allowed to happen, it has to be checked by a group of people called an Ethics Committee. They make sure the research is okay to do. This project has been checked by the xxx Research Ethics Committee.
### Do I have to take part?

No. It is up to you and your mum or dad or the person that takes care of you if you want to take part. If you do want to take part your mum or dad or the person that takes care of you will sign a form to say that everyone agrees.

### What will happen when I come into hospital?

When you come to the hospital the Doctors and Nurses will do some tests.

- Insert a picture of the hospital here:

Half of the people in the study will wear the pressure garments and the other half will not. Everyone in the study will have creams, massage, and movement exercises to help improve the scar.

<table>
<thead>
<tr>
<th>We will check to see how your scar is healing by:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Massaging the scar</strong></td>
</tr>
<tr>
<td><strong>Putting cream on the scar</strong></td>
</tr>
</tbody>
</table>
To see how your skin is healing the Doctor or Nurse will also take some photos with a camera, of your scars.

If you take part in this project you will need to come into hospital six times in a year. You will visit the hospital at the same time that would usually see your Doctor or Nurse.

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Week 2</th>
<th>Month 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Month 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Month 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Month 12</td>
</tr>
</tbody>
</table>

**Who will look after me when I come to the hospital?**

<table>
<thead>
<tr>
<th>XXXX is a doctor who helps people who have had a burn</th>
<th>Insert photo of Mr Moieman here</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Insert photo here</th>
<th>XXXX is a XXXX who helps people who have had a burn</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
xxxx is a xxxx who helps people who have had a burn

Insert photo here

xxxx, xxxx and xxxx are here to help you and you are not sure about something you can ask them any questions.

**Might anything about the research upset me?**

Sometimes the pressure garments can make your skin feel itchy; if they do you should tell your doctor or nurse.

We would like to ask you some questions about how you are feeling; if this does upset you can speak to your mum or dad, the person that looks after you, or the Doctor or Nurse.

**Will joining in help me?**

We cannot promise the study will help you but the things we find out from helping you might help treat children and young people with burns in the future.

**What if I get worried about anything?**

If you are worried about anything you can speak to your mum or dad, the person that looks after you or your Doctor or Nurse.
### Will anyone else know I'm doing this?

We won’t tell anyone else unless they need to know about your care. We will tell your Family Doctor (GP) that you are taking part in a research project.

### What if I don’t want to do the research anymore?

It is okay if you don’t want to do the research anymore, you can stop at any time, just tell your mum or dad or person that looks after you, or the doctor or nurse. Nobody will be upset and you the doctor and nurse will still help to look after you.

### Thank you!
## IDENTIFYING DETAILS

<table>
<thead>
<tr>
<th>Trial No.:</th>
<th>Participant initials:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Date of visit:</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

## TIMEPOINTS

Please indicate below, which visit this CRF relates to

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Visit 2, Month 1</th>
<th>Visit 4, Month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Visit 1, Week 1</th>
<th>Visit 3, Month 3</th>
<th>Visit 5, Month 12</th>
</tr>
</thead>
<tbody>
<tr>
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## VANCOUVER SCAR SCALE – SCAR 2

Using the Body Map mark and label the burn areas. The burns marked and labelled will be followed throughout the trial. A scar assessment using the adapted Vancouver Scar Scale below should then be completed for each of the burn sites. Please circle the most appropriate number in each one of the columns.

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Continuation forms should be used for those patients that have more than one scar site.
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<thead>
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<th>Pliability</th>
<th>Height</th>
<th>Vascularity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Normal</td>
<td>0 Normal</td>
<td>0 Flat</td>
<td>0 Normal</td>
</tr>
<tr>
<td>1 Hypopigmented</td>
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<tr>
<td></td>
<td>4 Ropes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 Contracture</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**THE PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS) – SCAR 2**

**Observer scale**

**Burn site number 2**
Continuation forms should be used for those patients that have more than one scar site.

![Diagram of human body and hand with scar assessments](image)

1 = Normal Skin  
10 = Worst Scar Imaginable

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<td>Relief</td>
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<tr>
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</table>

PEGASUS CRF Continuation Sheet

Version 1.2, 25th March 2015

Page 3 of 11
### Patient scale, to be completed only for adult patients (≥ 16 years old)

**Burn site number 2**  
Continuation forms should be used for those patients that have more than one scar site.

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<th>10</th>
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<tbody>
<tr>
<td>Has the scar been painful the past few weeks?</td>
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<tr>
<td>Has the scar been itching the past few weeks?</td>
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<tr>
<td>Is the stiffness of the scar different from your normal skin at present?</td>
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<td></td>
</tr>
<tr>
<td>Is the scar more irregular than your normal skin at present?</td>
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<td>What is your overall opinion of the scar compared to normal skin?</td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

1 = no, not at all  
10 = yes, very different

1 = no, as normal skin  
10 = yes, very different

1 = as normal skin  
10 = very different
**PAEDIATRIC PAIN AND ITCH SCALES – SCAR 2**

Pain and itch scales are to be completed by paediatric patients who cannot complete the POSAS Patient Scale

**Paediatric Itch Scales**
Please ask the patient to complete the scale most appropriate for their age and/ or level of understanding. NB: Only one of the itch assessment scales below needs to be completed.

If these assessment is cannot be completed please tick here: [ ]

**Paediatric Itch Scale – Younger Patients.** Please circle the most appropriate number.

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Comfortable, no itch</td>
</tr>
<tr>
<td>1</td>
<td>Itches a little; does not interfere with activity</td>
</tr>
<tr>
<td>2</td>
<td>Itches more; sometimes interferes with activity</td>
</tr>
<tr>
<td>3</td>
<td>Itches a lot; difficult to be still, concentrate</td>
</tr>
<tr>
<td>4</td>
<td>Itches most terribly; impossible to sit still, concentrate</td>
</tr>
</tbody>
</table>

**Paediatric Itch Scale – Older Patients.** Please mark level of itch as appropriate.

![Itch Scale Diagram]

- No itch
- 0 - 10 worst possible itch
  - None
  - Mild
  - Moderate
  - Severe
Paediatric Pain Scales
Please ask the patient to complete the scale most appropriate for their age and/or level of understanding. NB: Only one of the pain assessment scales below needs to be completed.

Paediatric Pain Scale – Younger Patients. Please circle the most appropriate number.

Paediatric Pain Scale – Older Patients. Please mark level of pain as appropriate.
**VANCOUVER SCAR SCALE – SCAR 3**

Using the Body Map mark and label the burn areas. The burns marked and labelled will be followed throughout the trial. A scar assessment using the adapted Vancouver Scar Scale below should then be completed for each of the burn sites. Please circle the most appropriate number in each one of the columns.

**Burn site number 3**
Continuation forms should be used for those patients that have more than one scar site.

<table>
<thead>
<tr>
<th>Pigmentation</th>
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THE PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS) – SCAR 3

Observer scale

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Paediatric Itch Scale – Older Patients. Please mark level of itch as appropriate.

```
No itch          Worst possible itch
0    1    2    3    4    5    6    7    8    9    10
None  Mild  Moderate  Severe
```

None  Mild  Moderate  Severe
Paediatric Pain Scales
Please ask the patient to complete the scale most appropriate for their age and/or level of understanding. NB: Only one of the pain assessment scales below needs to be completed.

**Paediatric Pain Scale – Younger Patients. Please circle the most appropriate number.**

![Paediatric Pain Scale for Younger Patients]

**Paediatric Pain Scale – Older Patients. Please mark level of pain as appropriate.**

- No pain
- Mild
- Moderate
- Severe
- Worst possible pain
# PEGASUS CUTOMETER ASSESSMENTS

These assessments should only be completed for patients randomised at University Hospitals Birmingham or Birmingham Children’s Hospital.

## IDENTIFYING DETAILS

<table>
<thead>
<tr>
<th>Trial No.:</th>
<th>Participant initials:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

## FORM CANNOT BE COMPLETED

Please tick one of the boxes below if the form cannot be completed because the patient has either withdrawn consent or been lost to follow-up

- Withdrawn consent
- Lost to follow-up

## TIMEPOINTS

Please indicate below, which visit this CRF relates to

<table>
<thead>
<tr>
<th>Visit</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Visit 2, Month 1</td>
<td>Visit 4, Month 6</td>
</tr>
<tr>
<td>Visit 1, Week 1</td>
<td>Visit 3, Month 3</td>
<td>Visit 5, Month 12</td>
</tr>
</tbody>
</table>
**CUTOMETER DATA**

Using Cutometer programme R2, please record the percentage elasticity of each scar site/comparable normal skin site, you must ensure that the scar number matches that given on the VSS. The comparable normal skin site number should correspond to the scar number.

NB: If the patient has a scar/comparable site that should be assessed but cannot be, please indicate this in the ‘applicable but not completed column’.

<table>
<thead>
<tr>
<th>Scar Sites</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scar Number</td>
<td>Percentage Elasticity (%)</td>
<td>Not applicable</td>
<td>Applicable but not completed</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comparable Sites – Normal Skin</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparable Site Number</td>
<td>Percentage Elasticity (%)</td>
<td>Not applicable</td>
<td>Applicable but not completed</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Name of person who has completed this form (please print):

Signature of person who has completed this form:
QUALITY OF LIFE ASSESSMENTS
Separate EQ-5D or PedsQL and/or CHU9D questionnaires must be completed at the beginning of each visit

IDENTIFYING DETAILS

<table>
<thead>
<tr>
<th>Trial No.:</th>
<th>Participant initials:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<tbody>
<tr>
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</tr>
</tbody>
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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

FORM CANNOT BE COMPLETED
Please tick one of the boxes below if the form cannot be completed because the patient has either withdrawn consent or been lost to follow-up

<table>
<thead>
<tr>
<th>Withdrawn consent</th>
<th>Lost to follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TIMEPOINTS
Please indicate below, which visit this CRF relates to

<table>
<thead>
<tr>
<th>Visit 1, Week 1</th>
<th>Visit 3, Month 3</th>
<th>Visit 5, Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visit 2, Month 1</th>
<th>Visit 4, Month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Vancouver Scar Scale**

Using the Body Map mark and label the burn areas. The burns marked and labelled will be followed throughout the trial. A scar assessment using the adapted Vancouver Scar Scale below should then be completed for each of the burn sites. Please circle the most appropriate number in each one of the columns.

**Burn site number 1**
Continuation forms should be used for those patients that have more than one scar site.

<table>
<thead>
<tr>
<th>Pigmentation</th>
<th>Pliability</th>
<th>Height</th>
<th>Vascularity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Normal</td>
<td>0 Normal</td>
<td>0 Flat</td>
<td>0 Normal</td>
</tr>
<tr>
<td>1 Hypopigmented</td>
<td>1 Supple</td>
<td>&lt;2mm</td>
<td>1 Pink</td>
</tr>
<tr>
<td>2 Mixed</td>
<td>2 Yielding</td>
<td>2 – 5 mm</td>
<td>2 Red</td>
</tr>
<tr>
<td>3 Hyperpigmented</td>
<td>3 Firm</td>
<td>&gt;5mm</td>
<td>3 Purple</td>
</tr>
<tr>
<td>4 Ropes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Contracture</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### THE PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS)

**Observer scale**

*Burn site number 1*

Continuation forms should be used for those patients that have more than one scar site.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascularity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PALE</td>
</tr>
<tr>
<td>Pigmentation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HYPO</td>
</tr>
<tr>
<td>Thickness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>THICKER</td>
</tr>
<tr>
<td>Relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MORE</td>
</tr>
<tr>
<td>Pliability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SUPPLE</td>
</tr>
<tr>
<td>Surface Area</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EXPANSION</td>
</tr>
<tr>
<td><strong>Overall Opinion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 = Normal Skin  
10 = Worst Scar Imaginable
### Patient scale, to be completed only for adult patients (≥ 16 years old)

**Burn site number 1**  
Continuation forms should be used for those patients that have more than one scar site.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1= no, not at all</th>
<th>10 = yes, very different</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the scar been painful the past few weeks?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the scar been itching the past few weeks?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the scar colour different from the colour of your normal skin at present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the stiffness of the scar different from your normal skin at present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the thickness of the scar different from your normal skin at present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the scar more irregular than your normal skin at present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is your overall opinion of the scar compared to normal skin?</td>
<td>1 = as normal skin</td>
<td>10 = very different</td>
</tr>
</tbody>
</table>
PAEDIATRIC PAIN AND ITCH SCALES

Pain and itch scales are to be completed by paediatric patients who cannot complete the POSAS Patient Scale.

**Paediatric Itch Scales**
Please ask the patient to complete the scale most appropriate for their age and/or level of understanding. NB: Only one of the itch assessment scales below needs to be completed.

If these assessments cannot be completed please tick here: [ ]

**Paediatric Itch Scale – Younger Patients.** Please circle the most appropriate number.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfortable, no itch</td>
<td>Itches a little; does not interfere with activity</td>
<td>Itches more; sometimes interferes with activity</td>
<td>Itches a lot; difficult to be still, concentrate</td>
<td>Itches most terribly; impossible to sit still, concentrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Paediatric Itch Scale – Older Patients.** Please circle the most appropriate number.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No itch</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Paediatric Pain Scales**
Please ask the patient to complete the scale most appropriate for their age and/or level of understanding. NB: Only one of the pain assessment scales below needs to be completed.

**Paediatric Pain Scale – Younger Patients.** Please circle the most appropriate number.

<table>
<thead>
<tr>
<th>0</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO HURT</td>
<td>Hurts Little Bit</td>
<td>Hurts Little More</td>
<td>Hurts Even More</td>
<td>Hurts Whole Lot</td>
<td>Hurts Worst</td>
</tr>
</tbody>
</table>

**Paediatric Pain Scale – Older Patients.** Please circle the most appropriate number.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Light</td>
<td>Moderate</td>
<td>Severe</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Paediatric Pain Scale – Older Patients.** Please circle the most appropriate number.
**RANGE OF MOVEMENT ASSESSMENTS**

Please indicate below whether any previously identified reduced range of movement has improved, stayed the same or deteriorated. Where reduction or improvement is seen please enter the percentage of movement recorded for each affected joint if these measurements are done as standard.

**Hand and wrist**

If this assessment is not applicable please tick here: 

<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM Measurement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thumb MCPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thumb IPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index Finger MCPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index Finger PIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index Finger DIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle Finger MCPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle Finger PIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle Finger DIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ring Finger MCPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ring Finger PIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**RANGE OF MOVEMENT ASSESSMENTS**

Please indicate below whether any previously identified reduced range of movement has improved, stayed the same or deteriorated. Where reduction or improvement is seen please enter the percentage of movement recorded for each affected joint if these measurements are done as standard.

**Hand and wrist**

If this assessment is not applicable please tick here: [ ]

<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM Measurement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ring Finger DIPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Little Finger MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Little Finger PIPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Little Finger DIPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Wrist Flexion</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Wrist Extension</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Ulnar Deviation</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Radial Deviation</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Supination</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Pronation</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Right**

<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM Measurement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thumb MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Thumb IPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Index Finger MCPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Index Finger PIPJ</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>
RANGE OF MOVEMENT ASSESSMENTS

Please indicate below whether any previously identified reduced range of movement has improved, stayed the same or deteriorated. Where reduction or improvement is seen please enter the percentage of movement recorded for each affected joint if these measurements are done as standard.

Hand and wrist

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<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
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<th>Stayed same</th>
<th>ROM Measurement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Finger DIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle Finger MCPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle Finger PIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ring Finger DIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Little Finger MCPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Little Finger PIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Little Finger DIPJ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrist Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrist Extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulnar Deviation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radial Deviation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# RANGE OF MOVEMENT ASSESSMENTS

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## Hand and wrist

If this assessment is not applicable please tick here: □

<table>
<thead>
<tr>
<th></th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM Measurement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supination</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Pronation</td>
<td>□</td>
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### Lower Quadrant

<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM (%)</th>
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<tbody>
<tr>
<td>Hip Flexion</td>
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<td>Hip Extension</td>
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<tr>
<td>Hip Abduction</td>
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<td>Hip Lateral Rotation</td>
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<td>Ankle Dorsiflexion</td>
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<td>Ankle Plantar Flexion</td>
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<td>Forefoot Inversion</td>
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<td>Forefoot Eversion</td>
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<tr>
<td>Foot MTPJ</td>
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<tr>
<td>Big Toe IPJ</td>
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<td>Little Toe IPJ</td>
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<tr>
<td>Right Hip Flexion</td>
<td></td>
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</tbody>
</table>
## Lower Quadrant

<table>
<thead>
<tr>
<th>Movement</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>Hip Extension</td>
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<td>Hip Abduction</td>
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<td>Hip Lateral Rotation</td>
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<td>Hip Medial Rotation</td>
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</table>
## Upper Limb

<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM (%)</th>
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<tbody>
<tr>
<td>Left</td>
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<td></td>
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<tr>
<td>Scapulo-thoracic Elevation</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Scapulo-thoracic Depression</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Scapulo-thoracic Protraction</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Scapulo-thoracic Retraction</td>
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<td>Glenohumeral Extension</td>
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<td>Glenohumeral Lateral Rotation</td>
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<td>Glenohumeral Medial Rotation</td>
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<td>Glenohumeral Adduction</td>
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<td>Elbow Flexion</td>
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<tr>
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<td>□</td>
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<tr>
<td>Glenohumeral Flexion</td>
<td>□</td>
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</tbody>
</table>
### Upper Limb

If this assessment is not applicable please tick here: ☐

<table>
<thead>
<tr>
<th>ROM</th>
<th>Improved</th>
<th>Deteriorated</th>
<th>Stayed same</th>
<th>ROM (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glenohumeral Extension</td>
<td></td>
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<td></td>
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<tr>
<td>Glenohumeral Lateral Rotation</td>
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<tr>
<td>Glenohumeral Abduction</td>
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</tr>
<tr>
<td>Elbow Extension</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
COMPLIANCE REVIEW

Since their last visit has the patient complied with their scar management regime possibly including massage, moisturisation and silicone treatment?  

No ☐ Yes, fully ☐ Partially ☐

If partially, please indicate the estimated percentage compliance below, e.g. a patient that complied with their treatment regime three quarters of the time would have a 75 % compliance rate.

Estimated percentage compliance: ☐ ☐ ☐ %

![The next question should be completed only for those patients that have been randomised to the Pressure Garment Therapy arm]

If partially, please indicate the estimated number of hours that pressure garments were worn each day.

Estimated number of hours: ☐ ☐ hours

MEDICATION REVIEW

Has the participant started any new medications or stopped any existing medications in relation to their burn injury since the last visit?  

No ☐ Yes ☐

If yes, please answer all questions in the Medication Review section

Please indicate whether the patient is currently taking or has started or stopped any of the following medications:

<table>
<thead>
<tr>
<th>Medications</th>
<th>N/A</th>
<th>Continuing</th>
<th>Stopped</th>
<th>Started</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical analgesics for pain and itch relief</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Mild analgesics, e.g., paracetamol, aspirin, NSAIDs</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Moderate opioid analgesics, e.g., codeine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Opioid analgesics, e.g., morphine, fentanyl</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other analgesics, e.g., gabapentin, pregabalin</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Antihistamines, e.g., cetirizine, diphenhydramine, loratadine, chlorphenamine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
**ADVERSE EVENTS**

**Adverse events**

Since the last visit, has the participant been unwell or experienced any side-effects or other adverse events?  

If 'yes', please complete below:  
*If a previously recorded AE has resolved or changed since the last visit, please update the AE records.*

Please provide a brief description of event:

---

Did the event include any of the following?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rashes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itch/ pruritis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound breakdown/ ulceration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-lesion steroid injection for aggressive hypertrophic scars</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraesthesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergic reaction to pressure garment fabric</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contractures or joint deformities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical scar revision</td>
<td></td>
<td></td>
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<tr>
<td>Blisters</td>
<td></td>
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</tbody>
</table>

**Serious adverse events**

Since the last visit, has the participant experienced any serious adverse events?  

Please refer to Protocol Section 8 for further explanation.
### PRESSURE GARMENT THERAPY

**To be completed only for those patients that have been randomised to the PGT arm of the trial.**

**Was the patient fitted/ refitted for their pressure garments at this visit?**

- No [ ]
- Yes [ ]

**If yes, where will the pressure garments be made?**

- In house [ ]
- Externally [ ]

If the patient was refitted for pressure garments, record for which scar site number(s). Scar site number(s) must be the same as those used on the previous Vancouver Scar Scale:

<table>
<thead>
<tr>
<th>Scar site</th>
<th>Was/ were Pressure Garment(s) fitted?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No, not required</td>
</tr>
<tr>
<td>1</td>
<td>[ ]</td>
</tr>
<tr>
<td>2</td>
<td>[ ]</td>
</tr>
<tr>
<td>3</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

Other reason for not refitting pressure garments at this visit:

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### FURTHER INFORMATION ON CONSULTATION

Estimated time spent on consultation (please include the time actually spent on the consultation, the time spent writing up patient notes and/ or referral letters/ letters to the patients GP). Please do not include the time spent completing the study-specific CRF.

**Estimated time spent on consultation:** [ ] [ ] [ ] [ ]

**Profession of person performing the visit:**

- Consultant [ ]
- Nurse [ ]
- Other (please specify opposite) [ ]
- Occupational Therapist [ ]
- Physiotherapist [ ]
THE PEGASUS TRIAL
Parent/ Guardian Consent Form

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

| Patient Identification Number: | | | (This number should be added by site staff immediately after randomisation) |

Please initial each box to confirm consent or leave blank

| I confirm that I have read and understood the Parent/ Guardian Information Leaflet dated | | | |
| --- | --- | --- | |
| [ ] / [ ] / [ ] version [ ] for the above study. I have had the opportunity to think about the information, ask questions and have had these answered to my satisfaction. | | | |
| I understand that my child’s participation in this trial is voluntary and that I am free to withdraw them at any time, without giving a reason and without my child’s medical care or legal rights being affected. I understand that data collected up to my child’s time of withdrawal may be used. | | | |
| I understand that sections of my child’s medical notes or information related directly to my child’s participation in this trial may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my child taking part in research. I give permission for these individuals to have access to my child’s records. | | | |
| I understand that my child’s doctor will provide a copy of this consent form and personal information about my child’s progress, in confidence, to the central organisers at Birmingham Clinical Trials Unit (BCTU) for use in the PEGASUS Trial. | | | |
| I agree to my child’s GP being informed of their participation in the PEGASUS Trial. | | | |
| | | | |
| I understand that the information held and maintained by The Health and Social Care Information Centre and other central UK NHS bodies may be used to help contact my child or provide information about my child’s health status. To do this, I understand that my child’s name, postcode and date of birth will be shared with these central bodies. | | | |
| I agree for my child to participate in the PEGASUS Trial | | | |

<table>
<thead>
<tr>
<th>Name of participant</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Name of parent/ guardian giving consent</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Name of person taking consent</th>
<th>Date</th>
<th>Signature</th>
</tr>
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</table>
1 copy for the participant, original for the Investigator Site File, 1 copy to be retained in the hospital notes and 1 faxed to BCTU.
THE PEGASUS TRIAL
Parent/Guardian Information Leaflet

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

We would like to invite your child to take part in our research study. Before you decide whether you want them to take part we would like you to understand why the research is being done and what it would involve for your child. One of our team will go through the information leaflets with you and your child and will answer any questions you have. We’d suggest this should take about 30 minutes Please ask us if anything is unclear or if you would like more information. Taking part is voluntary and it is up to you and your child to decide whether or not you would like them to take part.

Part (1) tells you the purpose of this study and what will happen to you if you take part. Part (2) gives you more detailed information about the conduct of the study.

Part One

What is the purpose of the study?

The most common complication following burns reported in up to 70% of patients, is red and raised (hypertrophic) scarring. This study is designed to look at the use of pressure garment therapy in the prevention of hypertrophic scarring. Scarring occurs when the burn wounds are healed and can vary with age, race, genetic factors, burn type and depth. Some people’s scars remain flat and supple and others become lumpy and firm.

Currently a selection of scar treatments are used throughout the UK and the world, with each treatment claiming to be the most effective. Unfortunately due to the lack of research and evidence not one particular treatment can be described as being ‘the best’.

The following treatments claim to be the most effective:

- Pressure Garment Therapy
- Moisturisation (using moisturising creams and sun protection creams)
- Silicone (gels, creams, sheets and sprays)
- Massage

Pressure garments are bespoke Lycra® garments measured for and fitted by your scar management team and are recommended to be worn for 23 hours a day for up to 18 months.

Your child’s involvement will help us see whether or not, in the future we will be able to conduct a larger study to look at the whether using pressure garments with massage, moisturisation and silicone helps to flatten and soften burns scars or if using massage, moisturisation and silicone, without pressure garment therapy is just as effective.
Examples of Pressure garments:

Why has my child been invited to participate?

Your child has been asked to join our study because:
1. They have sustained a burn injury greater than 1% of your total body surface area (TBSA)
2. They are eligible for scar management therapy intervention.

The trial will be carried out across six specialist burns units throughout the UK. Some centres specialise in treating adults or children, whereas others treat both adults and children.

Does my child have to take part?

It is up to you and your child to decide to whether or not to join the study. We will describe the study and go through some information leaflets with you and your child. You are free to withdraw your child at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to my child if they take part?

Participation in this study is voluntary. If you and your child decide that they would like to take part, a member of the study team, will explain the study to you and answer any questions you might have. They will ask you some questions about your health and any medication you may be taking. You will then be asked to sign a consent form and if appropriate, your child will be asked to sign an assent form. You should only do this if you are happy that you understand the project and want to take part.

If you consent for your child to participate they will be randomly allocated to either:
- Pressure garment therapy with massage, moisturisation and silicone or;
- Massage, moisturisation and silicone

This means that there is a 50:50 chance (the same as tossing a coin) that your child may or may not be allocated to wear pressure garments.

Your child will be closely monitored at months one, three, six, nine and 12 over a 12 month period. The 12 month appointment will only be completed if this date is before September 2015 as analysis of the trial’s data will begin at this point.
At each visit (approx. 2 hours) your child’s assessments may include:

- Range of motion
- Measurement of their scar’s elasticity
- Photographs of their scar
- Completion of questionnaires

If you agree for your child to take part in the trial, their hospital visits will be at the times when they would normally have hospital visits for their burn injury.

**Expenses and Payments**

Your child will not receive any expenses or payments for being involved in the study or for attending the outpatient appointments. There will be no additional hospital visits to make for the trial and all hospital visits will be at times when you would normally have appointments for your burn injury, as such, there will be no provision for travel expenses. Participants are not expected to pay for any treatments during the course of the trial.

**What will I have to do?**

The most important part of the study is attending all of the appointments and to comply with your therapy treatment plan i.e. massage, moisturisation, silicone and Pressure Garment Therapy (the latter, if applicable).

**What alternative treatments are available?**

Currently pressure garment therapy is just one of a range of treatments used in scar management. At the moment we do not know whether it is the pressure garment therapy or a combination of massage, moisturising cream and silicone that are useful in preventing hypertrophic scars.

**What are the possible disadvantages and risks of taking part?**

There are no associated risks with being involved in the study as all the procedures we are planning to perform are frequently performed in the hospital. In a small number of patients a rash may develop following the use of pressure garments and/or silicone. If this happens please inform your child’s doctor, nurse or therapist and your treatment will be reviewed.

**What are the possible benefits of taking part?**

We are unable to guarantee any direct benefit to participants that take part in this trial. Nonetheless, your child will be contributing to an improved understanding of scar management therapy. The information gained from this trial will also contribute to further studies and may help improve the treatment of people with a burn injury in the future.

**Part Two**

**What if relevant new information becomes available?**

Sometimes we get new information about the treatment being studied. We will tell you and your doctor about it and give you and your child an opportunity to discuss it with a trial nurse or doctor. If this new information means that we should stop the study, or change how we are running it, we will do this and make sure that your child is offered the best treatment.
What will happen if I don’t want to carry on with the study?
You are free to withdraw your child from the study at any time and this will not affect their care. You can either withdraw your child completely or choose to keep in contact with us to let us know their progress. Information collected earlier in the study may still be used.

What if there is a problem?
If you have concerns about any aspect of this study, you should ask to speak to the research coordinator who will do her best to answer your questions (contact numbers below).

We do not anticipate that anything will go wrong. We will of course take great care that nothing goes wrong but if your child is harmed by taking part in this research you should understand that there are no special compensation arrangements. If your child is harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you: ask to speak to the complaints manager of the hospital.

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions (insert Local PI contact details here). If you remain unhappy and wish to complain formally you can contact your local Patient Advice and Liaison Services (PALS) group or local equivalent group (insert name where applicable) (insert contact details here).

Quality of life assessment
It is important for us to understand the effect of your child’s scarring and treatment on their quality of life so that we can provide future patients with information on what they can expect to experience.

If your child is aged between five and 15 years old, they may be asked to complete a questionnaire about their general well-being. If your child is aged between two and four years old, we may ask you to complete a questionnaire on their behalf.

If your child is completing their own questionnaire, because only they truly know how they feel, we would like them to complete the questionnaire without input from family, loved ones or their clinical team. It is important to note that the data will be anonymised – no-one outside the research team will be able to identify your personal responses. The information you provide will be managed by the research team and summarised in reports at the end of the study.

This information will not be used to inform your child’s clinical care directly; therefore, it is important that you let your clinical team (GP, nurse or hospital consultant) know if you have any concerns regarding their wellbeing. Support can also be found from: [Please add appropriate support info e.g. PALS]

Will my taking part in this study be kept confidential?
We will follow ethical and legal practice and all information about your child will be handled in confidence. If you agree for your child to take part, their doctor will send basic information about your child and their condition to the PEGASUS Trial Office at the University of Birmingham Clinical Trials Unit (BCTU), on paper and electronically, where it will be securely stored under the provisions
of the Data Protection Act 1998 and/or applicable laws and regulations. Information held by the NHS may be used to follow your progress. The study data may also be looked at by representatives of regulatory authorities and by other authorised people to check that the study is being carried out correctly. Your family GP, and other doctors involved in your child’s clinical care, will be kept informed. All those associated with the study will have a duty of confidentiality to you as a research participant.

In line with Good Clinical Practice Regulations, at the end of the study, the data will need to be securely archived for at least 5 years (but ideally not less than 25 years). Arrangements for confidential destruction will then be made.

**Involvement of the General Practitioner/Family Doctor (GP)**
You will be asked to give permission for us to tell your GP on your child’s behalf.

**What will happen to the results of the research study?**
The results will be published in medical journals or presented at medical conferences. All the information we present will continue to be anonymous. If you wish to be informed of the results of the study, please inform the research staff and we can ensure that this happens at the end of the study once all the information has been analysed.

**Who is organising and funding the research?**
The study is being coordinated by the University of Birmingham Clinical Trials Unit and is funded by the National Health Research’s Health Technology Assessment Programme (project number 12/145/04).

The research doctors will not receive a payment for including you in this study.

**Who has reviewed the study?**
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands Ethics Committee.

**Further information and contact details**
If you require any further information please contact the research team on the details below. If you would prefer to speak to an independent person, regarding the trial please contact the Patients Advice and Liaison Service (PALS) on xxx xxx xxxx

**Contact Details for research team:**

- **Principal Investigator**
- **Research Nurse**
- **Scar Management Therapist**
THE PEGASUS TRIAL
Optional Parent/ Guardian Consent Form – Future Research

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

Patient Identification Number: [ ] [ ] [ ]
(This number should be added by site staff immediately after randomisation)

Please initial each box to confirm consent or leave blank

<table>
<thead>
<tr>
<th>I agree to my child being contacted in the future about other possible research trials.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial here ↓</td>
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</table>

<table>
<thead>
<tr>
<th>Name of participant</th>
</tr>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Name of parent/ guardian giving consent</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Name of person taking consent</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

1 copy for the participant, original for the Investigator Site File, 1 copy to be retained in the hospital notes and 1 faxed to BCTU

PEGASUS Parent/Guardian Optional Consent Form V1.0, 1st October 2014
### IDENTIFYING DETAILS

<table>
<thead>
<tr>
<th>Trial No.:</th>
<th>Participant initials:</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Hospital Name:</th>
<th>Principal Investigator:</th>
<th>Date of visit:</th>
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<tbody>
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</tbody>
</table>

### TIMEPOINTS

Please indicate below, which visit this CRF relates to

<table>
<thead>
<tr>
<th>Visit 1, Week 1</th>
<th>Visit 3, Month 3</th>
<th>Visit 5, Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Visit 2, Month 1</th>
<th>Visit 4, Month 6</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

### 1. Are you currently (please tick one option)

- Employed full-time [ ]
- Employed part-time [ ]
- Self-employed [ ]
- Retired [ ]
- Full-time parent/guardian [ ]
- Full-time carer [ ]
- Unemployed [ ]
- Student in full time education [ ]

Other (please specify): ___________________________________________________________________

If you are currently in any form of employment please complete questions 1a, 1b & 1c. Otherwise, please move to question 2.

> 1a. What is your job title? ___________________________________________________________________

> 1b. Since your last appointment at this clinic, how many days of work have you missed because of your burn injury?  

- 0 days [ ]
- Half a day [ ]
- 1 or more full days, please specify ______ Number

> 1c. If you are currently in employment:  
Since your last appointment, how much of the time at work did your burn injury make it difficult for you to do the following? (Please tick an appropriate box for each item)
All of the time (100%) | Most of the time | Half of the time (50%) | Some of the time | None of the time (0%)
---|---|---|---|---
**Time Management** (ability to handle time and scheduling demands of the job) | | | | |
**Physical work** (ability to perform job tasks involving bodily strength, movement, endurance, coordination & flexibility) | | | | |
**Mental** (ability to perform cognitive job tasks) | | | | |
**Interpersonal** (ability to perform interpersonal job tasks) | | | | |
**Output** (ability to produce work output in a high quality and timely manner) | | | | |

2. Since your last appointment, have you seen a doctor at your doctor’s surgery OR seen a doctor at home for any reason relating to your health?

Yes ☐ (complete 2a, 2b & 2c)  No ☐ (move to Q3)

> 2a. IF YES: How many times have you...

  Seen a doctor at the surgery Number
  Have you been visited at home by a doctor Number

> Were any of these visits related specifically to your burn injury?

> 2b. IF YES: How many surgery visits? Number > 2c. IF YES: How many home visits? Number

3. Since your last appointment, have you seen a nurse at your doctors surgery OR seen a nurse at home for any reason relating to your health?

Yes ☐ (complete 3a, 3b & 3c)  No ☐ (move to Q4)

> 3a. IF YES: How many times have you...

  Seen a nurse at the surgery Number
  Have you been visited by a nurse at home Number

> Were any of these visits related specifically to your burn injury?

> 3b. IF YES: How many visits to the surgery? Number > 3c. IF YES: How many home visits? Number
4. Since your last appointment, have you been to hospital for any reason relating to your health (other than this appointment today)?

Yes ☐ (complete 4a & 4b)  No ☐ (move to Q5)

> 4a. IF YES: How many times have you been to hospital? 

> 4b. IF YES: How many of these visits related to your burn injury? 

> 4c. IF YES: please provide details (e.g. A&E)

> 5. Since your last appointment at this clinic, have you received physiotherapy?

Yes ☐ (complete 5a)  No ☐ (move to Q6)

> 5a. IF YES: How many times? 

> 5b. IF YES: How many times related to your burn injury? 

> 5c. IF YES: Please tick a box below relating to the provider?

NHS at the hospital ☐  NHS at home ☐  Private (I paid) ☐

6. Since your last appointment at this clinic, have you received any counselling?

Yes ☐ (complete 6a, 6b & 6c)  No ☐ (move to Q7)

> 6a. IF YES: How many times? 

> 6b. IF YES: How many times related to your burn injury? 

> 6c. IF YES: Please tick a box below relating to the provider?

NHS at the hospital ☐  NHS at home ☐  Private (I paid) ☐
7. Since your last appointment has your **GP prescribed** any medicines or creams for your burn injury? (Do not include creams or medicines provided today as part of the research study)

<table>
<thead>
<tr>
<th>Type of item</th>
<th>Name of item (e.g. Ibuprofen)</th>
<th>Cost to you (i.e. prescription cost – could be £0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Painkiller</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Moisturiser</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Antibiotics</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Sun cream/block</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>£</td>
</tr>
</tbody>
</table>

8. Since your last appointment, have you **bought** any additional medicines, creams, gadgets, or clothing over the counter (without prescription), because of your burn injury?

<table>
<thead>
<tr>
<th>Type of item</th>
<th>Name of item (e.g. Paracetamol)</th>
<th>Cost to you</th>
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<tr>
<td>Alternative / complementary therapy</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Clothing (specifically relating to your burn injury)</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Vitamin Supplement</td>
<td></td>
<td>£</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>£</td>
</tr>
</tbody>
</table>

9. Since your last appointment, how much have you spent on care because you have been unable to look after a child or dependent due to your burn injury? (Include any care you have arranged in order to attend this appointment and similar appointments)

I do not have children or a dependent ☐
(i.e. not applicable)

Not needed any childcare/other care ☐ Had only informal childcare/other care ☐ I have spent £______ on childcare/other care
10. About how you travelled to this appointment

<table>
<thead>
<tr>
<th></th>
<th>One way □</th>
<th>Return □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of bus tickets</td>
<td>£</td>
<td></td>
</tr>
<tr>
<td>Cost of rail tickets</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Car parking charges</td>
<td>£</td>
<td></td>
</tr>
</tbody>
</table>

Has another adult accompanied you to the hospital today?
Yes □ No □

> IF YES: Have they taken time away from work or from caring for a dependent?)
Yes □ No □

11. If you have any further comments please use the box below...

THANK YOU!

When completed please return to a member of the study team
PEGASUS
Patient Resource Use Questionnaire
(Parents/ guardians of patients aged 15 years and under)

<table>
<thead>
<tr>
<th>IDENTIFYING DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial No.:</td>
</tr>
<tr>
<td>Hospital Name:</td>
</tr>
<tr>
<td>Principal Investigator:</td>
</tr>
<tr>
<td>Date of visit:</td>
</tr>
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</table>

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<thead>
<tr>
<th>TIMEPOINTS</th>
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<tbody>
<tr>
<td>Please indicate below, which visit this CRF relates to</td>
</tr>
<tr>
<td>Visit 1, Week 1</td>
</tr>
<tr>
<td>Visit 2, Month 1</td>
</tr>
</tbody>
</table>

1. Are you currently (please tick one option)

- Employed full-time □ 0
- Employed part-time □ 1
- Self-employed □ 2
- Retired □ 3
- Full-time parent/guardian □ 4
- Full-time carer □ 5
- Unemployed □ 6
- Student in full time education □ 7
- Other (please specify): 8

If you are currently in any form of employment please complete questions 1a & 1b. Otherwise, please move to question 2.

> 1a. What is your job title?

> 1b. Since your child’s last appointment at this clinic, how many days of work have you missed because of your child’s burn injury (e.g. providing care at home and attending appointments such as this one)?

- 0 days □
- ½ a day □
- If 1 or more full days, please specify □

Number
2. Is your partner / your child’s other parent currently:

Employed full-time □ 0  
Employed part-time □ 1  
Self-employed □ 2  
Retired □ 3  
Full-time parent/guardian □ 4  
Full-time carer □ 5  
Unemployed □ 6  
Student in full time education □ 7

Other (please specify): 8

If your partner / your child’s other parent is currently in any form of employment please complete questions 2a &2b. Otherwise, please move to question 3.

> 2a. What is their job title?

> 2b. Since your child’s last appointment at this clinic, how many days of work have they missed because of your child’s burn injury (e.g. providing care at home and attending appointments such as this one)?

0 days □  ∙ ½ days □  If 1 or more full days, please specify [ ]  Number  Don’t know □

3. Since their last appointment, has your child been seen by a doctor at their doctor’s surgery OR been seen a doctor at home for any reason relating to their health?

Yes □ (complete 3a,3 &3c)  No □ (move to Q4)

> 3a. IF YES: How many times in total have they...

    Seen a doctor at the surgery  [ ] Number  Have they been visited at home by a doctor  [ ] Number

    > IF YES: How many of these visits related specifically to their burn injury?

> 3b. How many surgery visits?  [ ] Number  > 3c. How many home visits?  [ ] Number

4. Since their last appointment, has your child been seen a nurse at their doctors surgery OR seen a nurse at home for any reason relating to their health?

Yes □ (complete 4a,4b & 4c)  No □ (move to Q5)

> 4a. IF YES: How many times in total have they...

    Seen a nurse at the surgery  [ ] Number  Have they been visited by a nurse at home  [ ] Number

    > IF YES: Were any of these visits related specifically to their burn injury?

> 4b. How many visits to the surgery?  [ ] Number  > 4c. How many home visits?  [ ] Number
5. Since their last appointment, has your child been to hospital for any reason relating to their health (other than this appointment today)?

Yes □ (complete 5a, 5b & 5c)  No □ (move to Q6)

> 5a. IF YES: How many times have they been to hospital?  Number

> 5b. IF YES: How many of these visits related to their burn injury?  Number

> 5c. Please give brief details (e.g. A&E)

6. Since their last appointment, has your child received physiotherapy?

Yes □ (complete 6a, 6b & 6c)  No □ (move to Q7)

> 6a. IF YES: How many times?  Number

> 6b. IF YES: How many times related to their burn injury?  Number

> 6c IF YES: Please tick the relevant box below regarding the provider of that physiotherapy?

   NHS at hospital □  NHS at home □  Private (I paid) □

7. Since their last appointment, has your child received any counselling?

Yes □ (complete 7a, 7b & 7c)  No □ (move to Q8)

> 7a. IF YES: How many times?  Number

> 7b. IF YES: How many times related to their burn injury?  Number

IF YES: Please tick the relevant box below regarding the provider?

   NHS at hospital □  NHS in the community □  Private (I paid) □

8. Since their last appointment, has your child’s GP prescribed any medicines or creams for their burn injury?  (Do not include creams or medicines provided today as part of the research study)

<table>
<thead>
<tr>
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9. Since their last appointment, have you bought any additional medicines, creams, gadgets, or clothing over the counter (without prescription), because of your child’s burn injury?

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<td>£</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>£</td>
</tr>
</tbody>
</table>

10. Since their last appointment, how much have you spent on childcare because of time away from school/nursery due to your child’s burn injury or childcare for a sibling whilst attending appointments?

Not needed any childcare □ Had only informal childcare □ I have spent £_____ on childcare

11. About how you and your child travelled to this appointment

<table>
<thead>
<tr>
<th>Cost of bus tickets</th>
<th>Cost of rail tickets</th>
<th>Cost of taxi fares</th>
<th>Approximate mileage by car</th>
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</tr>
</thead>
<tbody>
<tr>
<td>£</td>
<td>£</td>
<td>£</td>
<td>Number</td>
<td>£</td>
</tr>
<tr>
<td>One way □</td>
<td>One way □</td>
<td>One way □</td>
<td>Return □</td>
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<tr>
<td>Return □</td>
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</tbody>
</table>

11a. Has another adult accompanied you and your child to the hospital today?  
Yes □ No □

> 11b. IF YES: Have they taken time away from work or from caring for a dependent?)  
Yes □ No □

> 11c. IF YES: Have they incurred additional travel costs (not listed above)? (Please summarise with amounts)

12. If you have any further comments please use the box below...
THANK YOU!

When completed please return to a member of the study team
### SITE DETAILS

<table>
<thead>
<tr>
<th>Hospital:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomising clinician:</td>
</tr>
<tr>
<td>Name of person completing this form:</td>
</tr>
</tbody>
</table>

### PATIENT IDENTIFICATION DETAILS

<table>
<thead>
<tr>
<th>Has the patient consented to allow their full name to be given?</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Gender: Male</th>
<th>Female</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Date of birth: D M M Y Y Y Y Y</th>
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<tr>
<th>Hospital number:</th>
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<thead>
<tr>
<th>NHS number:</th>
<th></th>
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</table>

### ELIGIBILITY CHECKLIST

If any of the shaded boxes are ticked, the patient is NOT eligible for randomisation into the PEGASUS Study

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
</table>

**The patient is an adult or child who has had a burn injury ≥ 1 % of their total body surface area.**

**The patient has either: 1) been treated with split thickness grafts or 2) conservatively managed burn wounds or 3) donor sites which have taken > 2 weeks to heal.**

**The patient has been identified as having potential for hypertrophic scarring.**

**The patient is considered suitable for Scar Management Therapy.**

**Can the patient read, write and understand English?**

**Does the patient have a pre-existing skin condition that affects wound healing?**

**Does the patient have a history of Keloid Scarring?**

**Does the patient have a known allergy to Lycra or any other components of pressure garments?**

**In the investigator’s opinion, the patient is suitable to participate in the trial and does not have any clinically relevant past medical history.**

**Eligibility criteria confirmed by (name):**

This must be confirmed by a medically qualified person.
CONSENT DETAILS

Has the patient/ patient’s parent or guardian given informed consent to participate in the study? (If no, this patient cannot be randomised)

- No
- Yes

Version of informed consent form used:

Date of patient consent:

RANDOMISATION TO TREATMENT ALLOCATION

Online randomisation: www.trials.bham.ac.uk/pegasus (24hrs)
Log on to the PEGASUS website and follow the instructions on screen
OR
Telephone randomisation: 0800 953 0274 (UK toll free), 9am to 5pm Mon-Fri.

RANDOMISED TREATMENT ALLOCATION (please tick one):

- Pressure Garment Therapy
- No Pressure Garment Therapy

PEGASUS Trial Number

Date of randomisation:

Randomisation Form completed by (signature):

You must have signed the trial signature and delegation log

Date:

Please return this completed form to the PEGASUS Trial Office, University of Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, School of Health and Population Sciences, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT
**PEGASUS Serious Adverse Event Form**

Fax to: 0121 415 9135

### IDENTIFYING DETAILS

<table>
<thead>
<tr>
<th>Trial No.:</th>
<th>Participant initials:</th>
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</thead>
<tbody>
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<table>
<thead>
<tr>
<th>Principal Investigator:</th>
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</table>

Is this the initial reporting of this SAE or a follow-up SAE Report? Tick as appropriate.

- Initial Report [ ]
- Follow-up Report [ ]

If follow-up give the SAE ref number: [ ]

### REASON FOR REPORTING SAE

<table>
<thead>
<tr>
<th>Seriousness of event (please provide a response to each question)</th>
<th>Yes</th>
<th>No</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If Yes, date of death: DD/MMM/YYYY</td>
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<tr>
<td>Cause of death:</td>
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<tr>
<td>Life threatening event</td>
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<tr>
<td>In-patient hospitalisation or prolongation of existing hospitalisation</td>
<td></td>
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<tr>
<td>If Yes, Initial [ ] Prolonged [ ]</td>
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<tr>
<td>If Yes, number of days spent in hospital as result of the SAE:</td>
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<tr>
<td>Persistent or significant disability/incapacity</td>
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<tr>
<td>Other pertinent medical reason for reporting?</td>
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<tr>
<td>If Yes, please specify:</td>
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</tr>
</tbody>
</table>

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PEGASUS_SAE Form

V1.0, 26th March 2015

Page 1 of 4
### DETAILS OF EVENT

**Date of onset:**  

**Date site first aware of event:**  

**Brief description of event/diagnosis:**

---

### TRIAL INTERVENTION

*Please indicate which arm the patient was randomised to*

**Was the trial intervention suspended?**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Tick if yes</th>
<th>Start date (dd/mmm/yyyy)</th>
<th>Stop date (dd/mmm/yyyy)</th>
<th>Tick if continuing</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pressure Garment Therapy</td>
<td>☐</td>
<td>DD/MMM/YYYY</td>
<td>DD/MMM/YYYY</td>
<td>☐</td>
</tr>
<tr>
<td>Pressure Garment Therapy</td>
<td>☐</td>
<td>DD/MMM/YYYY</td>
<td>DD/MMM/YYYY</td>
<td>☐</td>
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</tbody>
</table>
### TRIAL INTERVENTION CAUSALITY ASSESSMENT

*The assessment of causality must be confirmed by a physician so delegated and recorded on the Delegation Log*

<table>
<thead>
<tr>
<th>Causality Assessment (tick only one)</th>
<th>Action taken with study drug (tick only one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Unrelated to trial intervention</td>
<td>1) None</td>
</tr>
<tr>
<td>2) Unlikely to be related to trial intervention</td>
<td>2) Discontinued temporarily</td>
</tr>
<tr>
<td>3) Possibly related to trial intervention</td>
<td>3) Discontinued</td>
</tr>
<tr>
<td>4) Probably related to trial intervention</td>
<td></td>
</tr>
<tr>
<td>5) Definitely related to trial intervention</td>
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</table>

Please give reasons why you consider the event to be related to the intervention:

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### CONCOMITANT MEDICATION

*Please provide details of other medication the patient was taking prior to the event:*

<table>
<thead>
<tr>
<th>Drug Name (give generic name)</th>
<th>Indication</th>
<th>Start date (dd/mmm/yyyy)</th>
<th>Stop date (dd/mmm/yyyy)</th>
<th>Tick if continuing</th>
<th>Dose</th>
<th>Unit</th>
<th>Freq.</th>
<th>Route</th>
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</table>
### FINAL OUTCOME

<table>
<thead>
<tr>
<th>Resolved no sequelae</th>
<th>If Resolved, date of resolution: DD/MMM/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolved with sequelae</td>
<td>If Resolved, date of resolution: DD/MMM/YYYY</td>
</tr>
<tr>
<td></td>
<td>Specific sequelae: ________________________________</td>
</tr>
<tr>
<td>Continuing</td>
<td>If Continuing, please provide date of resolution on follow-up/final SAE form</td>
</tr>
<tr>
<td>Fatal</td>
<td>If fatal, date of resolution is the date of death</td>
</tr>
</tbody>
</table>

**Medical response to SAE:** please include **a) relevant investigation results, b) treatment of the SAE, c) whether or not the study drug was suspended.** Please address both points and attach copies of relevant reports.

### DETAILS OF PERSON REPORTING

<table>
<thead>
<tr>
<th>Signature of Person Reporting: (you must have signed the site delegation log)</th>
<th>Name of Person Reporting:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone Number:</td>
<td>Email Address:</td>
</tr>
<tr>
<td>Fax Number:</td>
<td>Date: DD/MMM/YYYY</td>
</tr>
</tbody>
</table>

Signature of Principal Investigator (if not reported by PI):

Completed by (name):

Signed: Date: DD/MMM/YYYY
When you/your child were recruited to take part in this study (about six months ago) you were advised that there were two treatment paths – Scar Management Therapy with Pressure Garment Therapy (PGT) and Scar Management Therapy without Pressure Garment Therapy (PGT). You/your child were randomly allocated to receive Scar Management Therapy with PGT.

On the following page we will give you some information about what it would have been like to receive Scar Management Therapy without PGT, you will then be asked if you would still have chosen pressure garment therapy for yourself/your child, had you been able to choose.

This questionnaire asks you about the value that you place on the treatment that you/your child are currently getting, using money as a measure of that value. It allows us to understand how good or bad you think the different possible experiences would be. This task is definitely not a way of setting prices. NHS treatment will always remain free.

There are no right or wrong answers; we are interested in your views.
The care that you/your child are receiving involves frequent visits to a nurse or occupational therapist and a number of appointments with the doctor, as needed. Care has included moisturisation, use of silicone gel, massage and stretches, advice about wearing sun cream and a tight fitting Lycra-based garment, worn for up to 23 hours per day.

Had you/your child been allocated to receive Scar Management Therapy without PGT, this would have involved the same number of visits to the nurse, occupational therapist and doctor. All other aspects of care would have been the same.

Although Scar Management Therapy with PGT is often used as routine care, there is little evidence PGT actually has a noticeable effect on scar healing. A summary of the two treatment paths is given below.

<table>
<thead>
<tr>
<th>Scar Management Therapy without PGT</th>
<th>Scar Management Therapy with PGT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Frequent visits to a nurse or occupational therapist</td>
<td>• Frequent visits to a nurse or occupational therapist</td>
</tr>
<tr>
<td>• Visits to the doctor as needed</td>
<td>• Visits to the doctor as needed</td>
</tr>
<tr>
<td>• Moisturisation, silicone gel &amp; stretches</td>
<td>• Moisturisation &amp; stretches</td>
</tr>
<tr>
<td>• Advice about sun cream</td>
<td>• Advice about sun cream</td>
</tr>
<tr>
<td></td>
<td>• Wearing a Lycra-based garment over the burn site for up to 23 hours per day</td>
</tr>
</tbody>
</table>

Both types of therapy are provided free on the NHS and will always stay free for all patients, however one way of measuring the value of the therapy you/your child have received so far is to ask you how much money you would be willing to pay for it. The information that you give us will in no way be used to set or change prices for healthcare, it is simply a way of exploring how good or bad you think the different treatments are.
Remembering that this is a hypothetical exercise (not real), but being careful to give a realistic answer, what would be the maximum **monthly** amount you would be willing to pay, out of your own pocket, for the care that you/your child are currently receiving? Please place a tick in the right hand side column, next to the maximum amount that you **would** be willing to pay per month for the duration of the treatment.

| Tick |  £0 | £2 | £4 | £6 | £8 | £10 | £12 | £14 | £16 | £18 | £20 | £25 | £30 | £35 | £40 | £45 | £50 | £60 | £70 | £80 | £90 | £100 | £120 | £140 | £160 | £180 | £200 | £250 | £300 | £350 | £400 | £450 | £500 |
|------|-----|----|----|----|----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|

**Task 1**

If you would be willing to pay more than £500, please state the exact amount: £ _________

**Task 2**

If you could pay a smaller amount per month to receive the same treatment **but without the tight fitting Lycra garment**, would you choose to do so?

- Yes, I would pay less and not have the tight fitting Lycra garment. And I would pay £ ______ per month for this treatment.
- No, I would not pay for care if it did not include the tight fitting Lycra garment

A huge thank you for taking the time to complete this additional questionnaire. It would be useful for us to understand how easy or difficult you found this task and also understand the reasons why you are willing to pay this amount, so please do feel free to provide feedback below:
When you/your child were recruited to take part in this study (about six months ago) you were advised that there were two treatment paths – Scar Management Therapy with Pressure Garment Therapy (PGT) and Scar Management Therapy without PGT. You/your child were randomly allocated to receive Scar Management Therapy without PGT.

This questionnaire asks you about the value that you place on scar management therapy without PGT, using money as a measure of that value. It allows us to understand how good or bad you feel the treatment is. This is definitely not a way of setting prices. NHS treatment will always remain free.

As a reminder, the care that you/your child are receiving involves frequent visits to a nurse or occupational therapist and a number of appointments with the doctor, as needed. Care has included moisturisation, use of silicone gel, massage and stretches and advice about wearing sun cream.

The treatment that you/your child is currently getting is provided free on the NHS and will always stay free for all patients, however one way of measuring the value of the treatment is to ask you how much money you would be willing to pay for it. The information that you give us will in no way be used to set or change prices for healthcare, it is simply a way of exploring how good or bad you think the different treatments are. There are no right or wrong answers; we are interested in your views.
Remembering that this is a hypothetical exercise (not real), but being careful to give a realistic answer, what would be the maximum **monthly** amount you would be willing to pay, out of your own pocket, for the care that you/your child are currently receiving? Please place a tick in the right hand side column, next to the maximum amount that you **would** be willing to pay per month for the duration of the treatment.

<table>
<thead>
<tr>
<th>Tick</th>
</tr>
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<tbody>
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<td>£0</td>
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<td>£450</td>
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<td>£500</td>
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</tbody>
</table>

If you would be willing to pay more than £500, please state the exact amount: £ __________

A huge thank you for taking the time to complete this additional questionnaire. It would be useful for us to understand how easy or difficult you found this task and also understand the reasons why you are willing to pay this amount, so please do feel free to provide feedback below:
THE PEGASUS TRIAL

Young Person’s Information Leaflet (11-15 Years)

A feasibility study and open pilot two-arm randomised controlled trial comparing Pressure Garment Therapy with no Pressure Garment Therapy for the prevention of abnormal scarring after burn injury (PEGASUS)

We would like to invite you to take part in our research study. Before you decide whether or not you’d like to take part, we would like you to understand why the research is being done and what it will involve for you. One of our research team will go through this information sheet with you and answer any questions you have. We’d suggest this should take about 30 minutes. If anything is not clear or you would like more information, do not hesitate to ask a member of the local research team (see contact details at the end of this leaflet). Talk to others about the study if you wish, such as friends or relatives, and take time to decide.

Part (1) of this information sheet tells you the purpose of this study and what it will involve for you if you decide to take part.

Part (2) gives you more detailed information about how the study works.

Part One

Why is this study being done??

This study is designed to look at the use of wearing pressure garments for the prevention of raised scarring after a burn injury. Pressure garments are tight, Lycra®-based dressings which may be worn once burn wounds have healed.

Examples of Pressure garments:

They are used in combination with other therapies, such as regular use of massage, moisturising creams and silicone to help flatten and soften your scars.

Sometimes we don’t know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The
results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

In this trial some patients will receive pressure garment therapy in addition to massage, moisturising cream and silicone whereas other patients will have massage, moisturising cream and silicone but will not wear pressure garments.

**Why have I been invited to take part?**
We’re asking you to take part because:
1. You have a burn greater than 1% of your total body surface area (TBSA)
2. You are eligible for scar management therapy intervention.

This research project will be carried out across six specialist burns units throughout the UK. Some centres specialise in treating adults or children, whereas others treat both adults and children.

**Do I have to take part?**
No, it is up to you and your parent(s) or guardian(s) to decide to join the study. We will describe the study and go through this information sheet. We will ask for your permission and ask your parent/guardian to sign a consent form. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this would not affect the care you receive.

**If I decide to take part, what will it involve?**
If you agree to participate you will be randomly allocated to either:
- Pressure garment therapy with massage, moisturisation and silicone or;
- Massage, moisturisation and silicone

This means that there is a 50:50 chance (the same as tossing a coin) that you may or may not be allocated to wear pressure garments.

You will be closely monitored at months one, three, six, nine and 12 over a 12 month period.

At each visit (approx. 2 hours) assessments may include:
- Range of motion (how you move)
- Measurement of your scar’s elasticity (how flexible it is)
- Photographs of your scar
- Completion of questionnaires

If you agree to take part in the trial, your hospital visits will be at the times when you would normally have hospital visits for your burn injury.

**If I choose not to take part in this study, what treatment would I receive?**
Pressure garment therapy is just one of a range of treatments that is used to help scarring in patients that have had a burn. At the moment we do not know whether it is the pressure garment therapy or a combination of massage, moisturising cream and silicone that are useful in helping with scarring.

**Is there anything to be worried about if I take part?**
There are no extra risks with being involved in the study as all the procedures we are planning to perform are often performed in the hospital and by your doctor, nurse and therapist.
Sometimes pressure garments and silicone can cause patients to develop an itch or a rash. If this happens please speak to your doctor, nurse or therapist and they will try to help you.

**What are the possible benefits of taking part?**
We cannot promise that taking part in this study will help you but the information that we get may help children and young adults, who have had a burn, in the future.

**Health and wellbeing**
It is very important for us to understand the effect that your scar(s) and treatment have on you so that we can help people that have had a burn injury in the future.

As part of the study we’d like to ask you to complete a questionnaire about you feel. We estimate that it will take around 10 minutes to complete the questionnaire.

Because only you truly know how you feel, we would like you to complete the questionnaire without input from family, loved ones or your doctor, nurse or therapist. The information we collect from you will be anonymised – no-one outside the research team will be able to identify your personal responses. We will write a report based on the information provide at the end of the study.

This information will not be used to inform your doctor, nurse or therapist; therefore, it is important that you let your parent(s)/ guardian(s), doctor, nurse or therapist know if you feel worried about anything.

*Thank you for reading so far – if you are still interested, please go to Part 2:*

**Part Two**

**What if relevant new information becomes available?**
It is unlikely that this will happen during the study but if this does happen your research doctor will tell you and discuss with you whether you should continue in the study.

**What will happen if I don’t want to carry on with the study?**
You can withdraw from the study at any time and it won’t have any effect on your medical care.

**What if there is a problem?**
If you are worried about any part of the study, you or your Parent/ Guardian can speak with the research nurse, or the local Patient Advice and Liaison Service (PALS) support group.

We will monitor your care very closely and if there is a problem your Doctor will explain what happens next.

**Will anyone else know I’m doing this?**
We will only tell those people that have a need or right to know. We will use a number instead of your name. We will only share information with your name, address, date of birth removed.

Your own family Doctor (GP) will be told that you and you Parent/Guardian have agreed to take part in the research study.

**What will happen to the results of the research study?**
The results of this study will be published in medical articles or presented at medical conferences. You will not be named in any of the information we present about this study. If you would like to find out the results of the study, please tell the research staff and they can make sure that this happens at the end of the study.

Who is organising and funding the research?
The study is being coordinated by the University of Birmingham Clinical Trials Unit and is funded by the National Health Research’s Health Technology Assessment Programme (project number 12/145/04).

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to make sure the research is okay to do. This study has been looked at and approved by the East Midlands REC.

Further information and contact details
If you require any further information you or your Parent/ Guardian can contact a member the research team on xxxx xxx xxxx, full contact details are given below.

If you or your Parent/ Guardian would like to speak to an independent person, regarding this research study or would like some advice about research in general, please contact the local PALS on xxxx xxx xxxx.

Principal Investigator

Nurse

Therapist