CLOTHES

Randomised controlled trial of silk therapeutic clothing for the long-term management of eczema in children

WORKSHEET

Participant Initials: | | | |

Participant ID: | | | | | |

Sponsor: University of Nottingham

General Instructions

Determining Eligibility

Visit 1 should be performed to determine the eligibility of the participant for inclusion into the trial. If at any point it is determined that the participant is not eligible for inclusion it is not necessary to continue with any further assessments.

Randomising

If all assessments have been performed and the patient is eligible:

- Proceed to enrol and randomise the patient by following this link: https://ctsu2.nottingham.ac.uk/1132/login.asp

Enrol the participant by entering the:

- Gender
- Date of Birth
- Initials
- Height in cm

  Then on the contacts page add:
- Contacts details and preference for either **online** or postal weekly questionnaires.

Once enrolled the participant will be assigned a unique participant ID. Please record this on the worksheet. It is only necessary to enrol participants who will be randomised.

Once the enrolment details and contact details have been added the participant can be randomised.

Completing the eCRF

Once the participant has been randomised please follow this this link and enter the visit 1 data within 7 days of the visit:
https://mcwapctu01.nottingham.ac.uk/macro/

The worksheets should be filed locally in a locked filing cabinet (there is no need to copy and send to the co-ordinating centre)

Serious Adverse Events

If the participant experiences any adverse events after being randomised these should be reported on the paper SAE form and faxed into the NCTU. Please see Trial Manual for Fax details.

Completing this worksheet

This is a worksheet to help collect the information in the clinic.
Worksheets will need to be retained if information is not being recorded into the patient's notes, as they constitute source data.

Participant initials | | | |

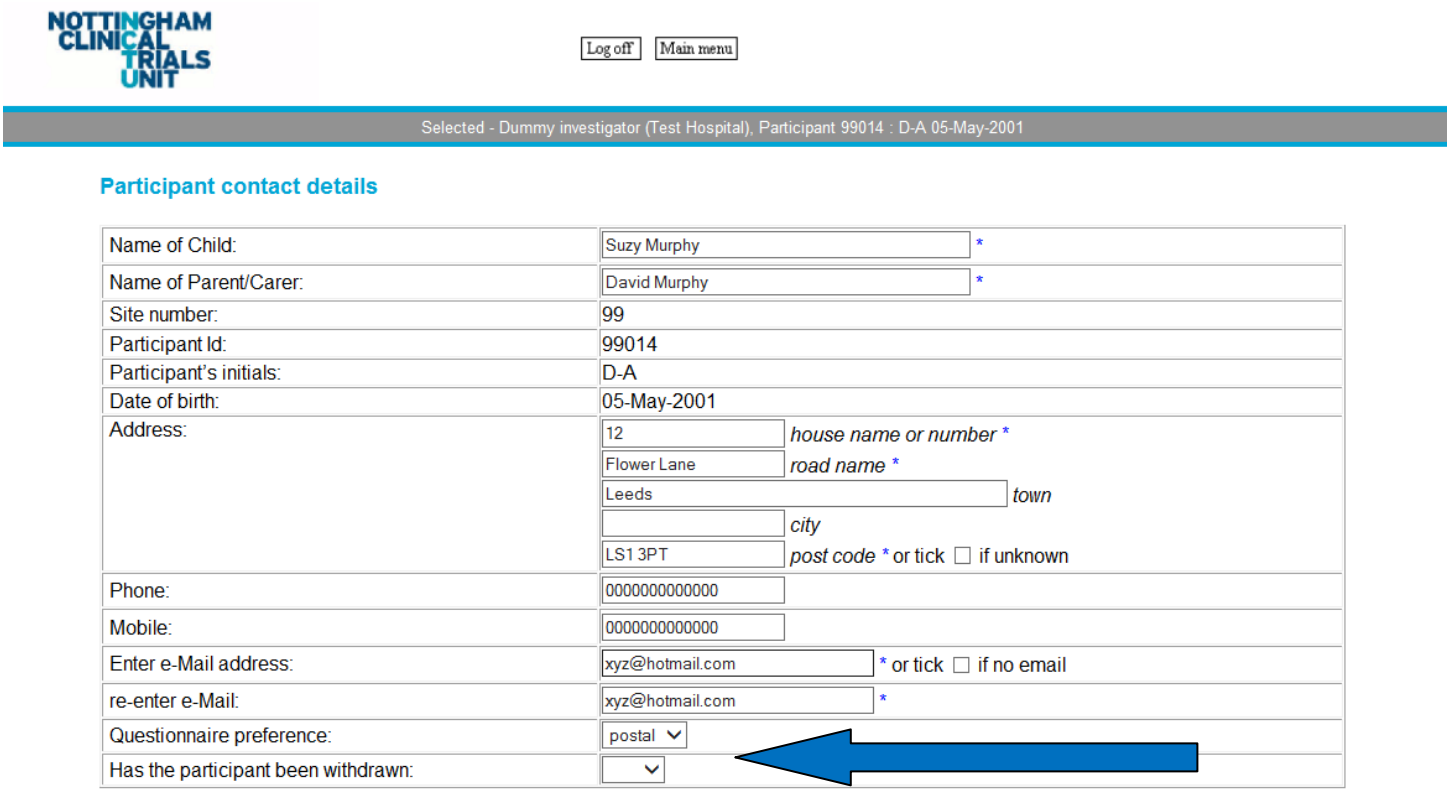
These should be recorded as 3 digits eg HKP, however if the participant does not have a middle initial it should be recorded as eg: H-P

Participant ID: | | | | | |

The 5 digit participant ID will be assigned once randomised, it is made up of 2 digit site ID followed by a sequential 3 digit number.

Online / Postal weekly questionnaires

- If at any point during the study the participant/parent/guardian wishes to change their preference for online questionnaires to postal or vice versa this can be updated on the contacts details page.
- If the participant is withdrawn from the study and therefore no longer wishes to receive the links/reminders for the questionnaires, the site or the trial manager are able to mark the participant as withdrawn.



Participant initials: ☐☐☐ VISIT 1 - BASELINE

Participant ID: ☐☐☐☐☐

VISIT INFORMATION	
Date of Visit:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY

INFORMED CONSENT			
Consent Type	**Was written Informed Consent obtained?**		**Date of Informed Consent** DD/MMM/YYYY
	Yes	**No**	
Study Informed Consent *(Mandatory)*	☐	☐	☐☐/☐☐☐/20☐☐
Informed Consent for Genetic Study *(Optional)*	☐	☐	☐☐/☐☐☐/20☐☐
Informed Consent for Storage of Genetic Samples *(Optional- if 'Yes' above question must also be Yes)*	☐	☐	☐☐/☐☐☐/20☐☐
Parent/Guardian agreed to be added to the Centre of Evidence Based Dermatology's mailing list *(Optional)*	☐	☐	☐☐/☐☐☐/20☐☐
Guardian/Parent would like to receive a copy of the study results *(Optional)*	☐	☐	☐☐/☐☐☐/20☐☐

DEMOGRAPHY		
Date of birth:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY	
Initials:	☐☐☐	
Gender:	Male ☐	Female ☐
Ethnicity (tick one only)	White ☐	Black (Other) ☐
	Indian ☐	Chinese ☐
	Pakistani ☐	Other Asian (non–Chinese) ☐
	Bangladeshi ☐	Mixed Race ☐
	Black Caribbean ☐	Other ☐
	Black African ☐	Not Given ☐

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

BASELINE CHARACTERISTICS			
		No	**Yes**
Does the child have a history of any of the following conditions?	Asthma	☐	☐
	Allergic rhinitis (hayfever, perennial rhinitis)	☐	☐
	Food allergy (eliminates a food from diet)	☐	☐
	Anaphylaxis (have an Epipen/Jext/Anapen)	☐	☐
What are the types/patterns of Eczema? (currently present)	Flexural	☐	☐
	Discoid	☐	☐
	Reverse Pattern	☐	☐
Where on the body is the Eczema? (at the moment)	Head and Neck	☐	☐
	Hands and Wrists	☐	☐
	Feet and Ankles	☐	☐
	Limbs	☐	☐
	Trunk	☐	☐
Has your child's eczema been previously treated by the following:	GP	☐	☐
	Secondary Care (dermatologist or other specialist)	☐	☐

- **To be eligible at least one patch of eczema should be present on the trunk or the limbs.**

UK DIAGNOSTIC CRITERIA			
In order to qualify as a case of atopic eczema with the UK diagnostic criteria, the child must have:	**No**	**Yes**	
1. Has child had an itchy skin condition in the last 12 months	☐	☐	
Plus three or more of:	**No**	**Yes**	**N/A**
2. Has child had onset below age 2 (not used in children under 4 years)	☐	☐	☐
3. Has child had a history of flexural involvement	☐	☐	
4. Has child had a history of a generally dry skin	☐	☐	
5. Has child had a personal history of asthma or hayfever (in children aged under 4 years, history of atopic disease in a first degree relative may be included)	☐	☐	
6. Visible flexural dermatitis as per photographic protocol	☐	☐	

- **See Trial Manual for guidance**

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

ECZEMA TREATMENT

- **Please only record medications used on the areas covered by the clothing, not those used on hands/feet**
- **If more than 2 medications for each category have been used in the last month please enter the most frequently used medication**
- **Main emollient/steroid/calcineurin inhibitors = most frequently used**
- **Please see emollient ladder/steroid ladders for classification of consistency/potency**

EMOLLIENTS

Has the child used Emollients on the body within the last month? No ☐ Yes ☐

Name of Emollient Used on Body	Consistency (tick one only)	Main Emollient?
1. _____	Light ☐ Creamy ☐ Greasy ☐ Very Greasy ☐	Yes ☐ No ☐
2. _____	Light ☐ Creamy ☐ Greasy ☐ Very Greasy ☐	Yes ☐ No ☐

Please see Emollient ladder for classification of medications into Light, Creamy, Greasy and Very Greasy

TOPICAL STEROIDS

Has the child used topical steroids on the body within the last month? No ☐ Yes ☐

Name of Steroid Used on Body	Potency (tick one only)	Main Steroid?
1. _____	Mild ☐ Moderate ☐ Potent ☐ Very Potent ☐	Yes ☐ No ☐
2. _____	Mild ☐ Moderate ☐ Potent ☐ Very Potent ☐	Yes ☐ No ☐

Please see Steroid ladder for classification of medications into Mild, Moderate, Potent or Very Potent.

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

CALCINEURIN INHIBITORS			
Has the child used Calcineurin Inhibitors on the body within the last month? eg Protopic (Tacrolimus), Elidel (Pimecrolimus) **No** ☐ **Yes** ☐			
Name of Calcineurin Inhibitor Used on Body	**Strength** (tick one only)		**Main Calcineurin Inhibitor?**
1. _____ _____	Mild ☐	Moderate ☐	Yes ☐ No ☐
2. _____ _____	Mild ☐	Moderate ☐	Yes ☐ No ☐

Protopic (Tacrolimus) = 0.03% = Mild

Elidel (Pimecrolimus) = 1% = Moderate

MEDICATIONS		
How many times have wet/dry wraps been used in the last month for their eczema? (tick one only) (this includes tubifast, itchopaste bandage)	None ☐	1-4 times ☐
	5-10 times ☐	>10 times ☐
	(Participant should be excluded if ≥ 5)	
Do you/your child use any other treatment in addition to Emollients, Steroids and Calcineurin Inhibitors for their eczema eg tablets, or antihistamines?	No ☐	Yes ☐
If yes, please specify	_____ _____	
Any new prescribable treatments used in the last month?	No ☐	Yes ☐
If yes, please specify e.g. methotrexate, cyclosporin, aziathioprine, light therapy, prednisolone, mycophenolate mofetil are prohibited medications	_____	

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

NOT FOR DATABASE

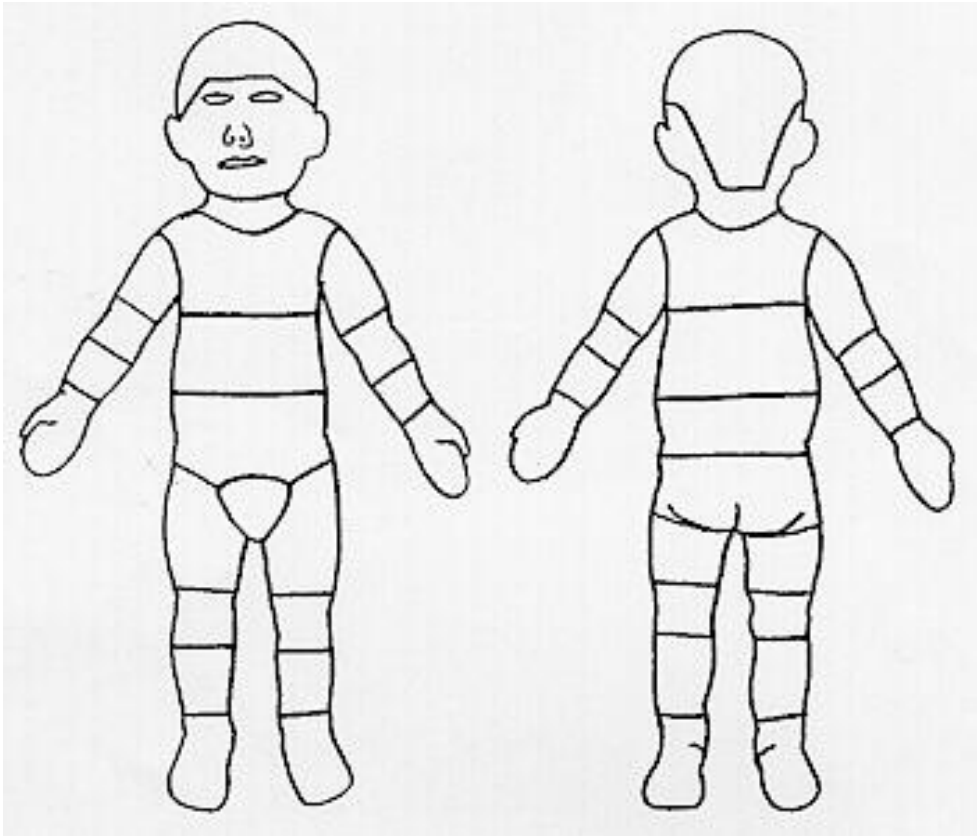
CHECKLIST		
Do you/your child currently use silk clothing for eczema?	No ☐	Yes ☐
If yes, prepared to stop using them?	No ☐ If No, then participant is not eligible	Yes ☐
Currently enrolled in any other trial?	No ☐ If Yes, then participant is not eligible	Yes ☐
Does the skin show signs of Infection?	No ☐ If yes, recommend that the patient contacts their normal medical team (GP, Nurse, dermatologist) as appropriate	Yes ☐

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

☐ **Mark if not done**

NOTTINGHAM ECZEMA SEVERITY SCORE (NESS)

Surface area measurement using tick boxes
Record a tick in each box if more than 2cm² (size of a 10 pence coin) is involved with AE. Calculate the total ticks by adding together the number of recorded ticks for both the front and back of the surface diagram. The final score is calculated using the table below.



Number of ticks	Score	Final score (tick one)
0-2	1	
3-5	2	
6-10	3	
11-20	4	
>20	5	

Participant initials:	VISIT 1 - BASELINE
Participant ID:	

1. Clinical Course (ask the Parent)

In the Last 12 months has your child's skin condition been:	Score (please circle one answer)
a). Present for less than 6 weeks in total?	1
b). Present for between 6 weeks and less than 3 months in total?	2
c). Present for between 3 months and less than 6 months in total?	3
d). Present for between 6 months and less than 9 months in total?	4
e). Present for more than 9 months in total?	5

2. Clinical Intensity (ask the Parent)

In the last 12 months, how often has your child's sleep usually been disturbed by itching or scratching due to their skin problem?	Score (please circle one answer)
a). Sleep is not usually disturbed	1
b). 1 night per week on average	2
c). 2 or 3 nights per week on average	3
d). 4 or 5 nights per week on average	4
e). 6 or more nights per week on average	5

3. Extent of Atopic Eczema by examination (see diagram opposite for details)

Score (please circle one answer)
1
2
3
4
5

4. Final Assessment severity

Mild: total score 3-8	
Moderate: total score 9-11	
Severe: total score 12-15	

- **If total score is 8 or less then they are not eligible to be included in the study.**

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

☐ **Mark if not done**

THREE ITEM SEVERITY SCALE (TIS)

Criteria	**Score** (tick one only)
Erythema	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐
Oedema / papulation	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐
Excoriation	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐

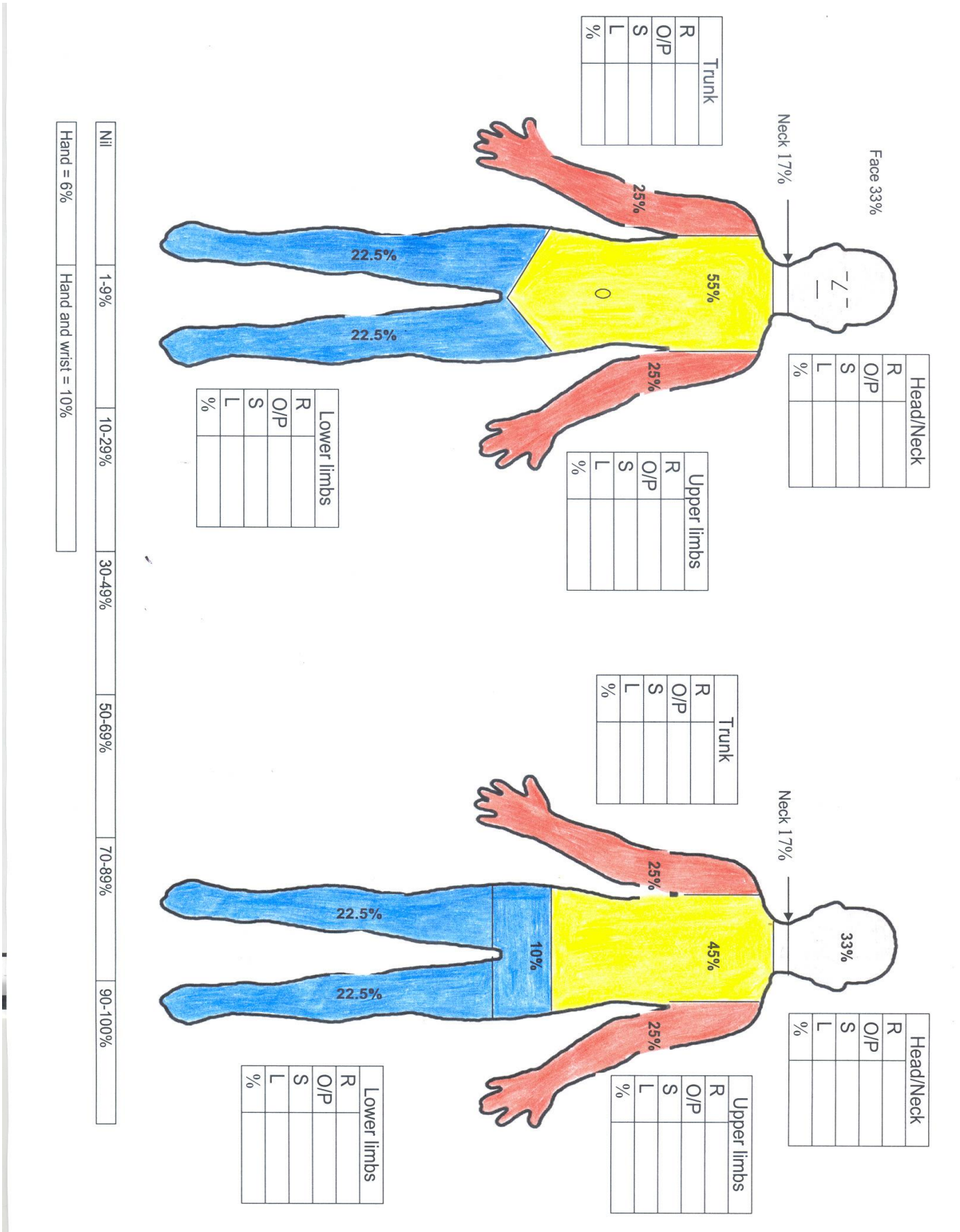
Representative Body Site: Choose one representative body site to assess all three signs. The representative site should be in an area covered by the clothing, and be the area that, in the view of the parent/participant, is most bothersome. The representative body site may change from visit to visit.

Total Score: ☐☐

Participant initials: | | | |

Participant ID: | | | | | |

VISIT 1 - BASELINE



Participant initials: ☐☐☐ VISIT 1 - BASELINE

Participant ID: ☐☐☐☐☐

☐ **Mark if not done**

- Assess each body area for **redness (erythema), papulation & oedema, scratching (excoriation) and lichenification (lined skin)**
- Using the photographic comparison table, assign a score for each of the signs in each of the four body areas. Assess each sign for the entire body region – so for example a patient may have grade 1 erythema in some areas, but grade 3 erythema in others. If that is the case, then the "average of the two" is taken and so the score become 2. Likewise, if they have some areas that are grade 2 and others that are grade 3, then the score becomes 2.5.
- Score the percentage area of each region affected by eczema

ECZEMA AREA AND SEVERITY INDEX (EASI)

Body Area	% Area affected by Eczema (tick one only)				Criteria	Score (tick one only)						
						Absent (0)	(0.5)	Mild (1)	(1.5)	Moderate (2)	(2.5)	Severe (3)
Head and Neck	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐
Upper Limbs	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐
Trunk	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐
Lower Limbs	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

HYPERLINEAR PALMS			
Hyperlinear palms?	No ☐	Yes ☐	Unsure ☐

Please see Trial Manual for details

☐ **Mark if not done**

INVESTIGATOR'S GLOBAL ASSESSMENT (IGA)

How is the child's eczema <u>today</u>?

☐	☐	☐	☐	☐	☐
Clear	Almost clear	Mild	Moderate	Severe	Very severe

	Tick when completed	**Completed by: (tick one only)**	
• **PATIENT'S GLOBAL ASSESSMENT (PGA) (included in 'Clinic Questions')** To be completed by parent/guardian or child Please request that where possible if the child performs the baseline assessment, the child completes the follow up questionnaires or if the parent/guardian performs the baseline assessment, the parent/guardian completes the follow up questionnaires.	☐	Parent/Guardian	☐
		Child	☐

Participant initials: ☐☐☐

Participant ID: ☐☐☐☐☐

VISIT 1 - BASELINE

INCLUSION CRITERIA		
To be eligible for this trial all the inclusion criteria must be answered Yes	**No**	**Yes**
1. Child aged 1 to 15 years at baseline.	☐	☐
2. Diagnosis of moderate or severe eczema (atopic dermatitis). Presence of eczema will be confirmed using the UK Diagnostic Criteria for Atopic Eczema and eczema severity judged using the Nottingham Eczema Severity Scale (NESS) (Score of 9 or above)	☐	☐
3. Resident within travelling distance of a recruiting centre.	☐	☐
4. Child should have at least one patch of eczema on the trunk or the limbs.	☐	☐
5. Parents/legal guardian able to give informed consent	☐	☐

EXCLUSION CRITERIA		
To be eligible for this trial all the exclusion criteria must be answered No	**No**	**Yes**
1. Child who has taken systemic medication (including light therapy) or oral steroids for eczema within the previous three months.	☐	☐
2. Child who has started a new treatment regimen within the last month.	☐	☐
3. Child who has used wet/dry wraps ≥5 times in the last month.	☐	☐
4. Child who is currently using silk clothing for their eczema and are unwilling to stop using the clothing during the trial.	☐	☐
5. Child who is currently taking part in another clinical trial.	☐	☐
6. Child who has expressed a wish not to take part in the trial.	☐	☐

Participant initials: | | | |

Participant ID: | | | | | |

VISIT 1 - BASELINE

NOT FOR DATABASE

SURVEY OF SKIN PROBLEMS – For Parents of children aged 3 and under

1. In the **last year**, has your child had an **ITCHY** skin condition – by *itchy* we mean scratching or rubbing the skin? □ Yes □ No

If you have answered "NO" please skip to Question 4
If you have answered "YES" please answer all the questions

2. At what age did your child's ITCHY skin condition start?

_____years _____ months

3. Has this skin condition **ever** affected the skin creases in the past – by *skin creases* we mean fronts of elbows, behind the knees, fronts of ankles, around the neck, or around the eyes?
□ Yes □ No

4. In the **last year**, has your child suffered from a **dry skin** in general?
□ Yes □ No

5. Does anyone in your child's immediate family (i.e. mother, father, brother or sisters) suffer from:
eczema? □ Yes □ No
hay fever? □ Yes □ No
asthma? □ Yes □ No

SURVEY OF SKIN PROBLEMS – For Parents of children aged 4 to 15 years

1. In the **last year**, has your child had an **ITCHY** skin condition – by *itchy* we mean scratching or rubbing the skin? □ Yes □ No

If you have answered "NO" please skip to Question 5
If you have answered "YES" please answer all the questions

2. Has your child had this ITCHY skin condition in the **LAST WEEK?**
□ Yes □ No

3. How old was your child when this skin condition began?
Under 2 [ ] 2 to 5 [ ] 6 to 10 [ ] Over 10 [ ]

4. Has this skin condition **ever** affected the skin creases in the past – by *skin creases* we mean fronts of elbows, behind the knees, fronts of ankles, around the neck, or around the eyes?
□ Yes □ No

5. In the **last year**, has your child suffered from a **dry skin** in general?
□ Yes □ No

6. Does anyone in your child's immediate family (i.e. mother, father, brother or sisters) suffer from:
eczema? □ Yes □ No
hay fever? □ Yes □ No
asthma? □ Yes □ No

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

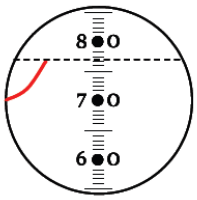
Please ensure Visit 1 Parent/Guardian/Child Questionnaires are completed during the visit:

	Tick when completed	**Completed by**	
• **PATIENT ORIENTED ECZEMA MEASURE (POEM)** To be completed by parent/guardian or child	☐	Patient /Guardian Child	☐ ☐
• **CLINIC QUESTIONS** To be completed by parent/guardian or child	☐		
• **DERMATITIS FAMILY IMPACT QUESTIONNAIRE (DFI)** To be completed by parent/guardian	☐		
• **EQ-5D-3L** To be completed by parent/guardian	☐	Which Parent/Guardian:	
• **THE CHILD HEALTH UTILITY 9 DIMENSIONS (CHU-9D)** To be completed by parent/guardian or child <u>for children of aged 5 or over only</u>	☐		
• **ADQoL** To be completed by parent/guardian or child	☐		
Comments on ADQoL:			

Participant initials: ☐☐☐	VISIT 1 - BASELINE
Participant ID: ☐☐☐☐☐	

EQ5D: 'Your Own Health State Today'

- If the line does not cross the scale, draw a horizontal line:



Even though the line does not cross the VAS this response can still be scored by drawing a horizontal line from the end point of the response to the VAS. In this example the response should be coded as 77

- If a circle is drawn, select middle of circle as the measurement.
- If the response is not clear, please record as 'missing

RANDOMISATION	
Participant randomised into the trial?	No ☐ Yes ☐ If yes please fill in participant ID on the front and at the top of each page.
The below information will need to recorded to enable randomisation of the participant, please also record all contact details on the contact sheet.	
Please record patient's height (cm)	☐☐☐
Please give details of child's build/clothing size (i.e. any info that will help trial team select the appropriate size clothing)	
Record preference for type of weekly questionnaires	Paper ☐
	Online ☐

Participant initials:	VISIT 1 - BASELINE
Participant ID:	

NOT FOR DATABASE

REMINDERS

- **Discuss with the participant/guardian/carer:**
  1. **If any visits occurred to a healthcare professional within the last 4 weeks**
  2. **If any prescriptions were made for eczema within the last 4 weeks**

  If the response is yes to any of the above please record on pages 33-38.

- **Discuss what will happen next**
- **Book an appointment for the next clinic visit**
- **If consent has been obtained to collect a saliva sample, has a sample been collected today and recorded on the sample collection page?**
- **File a copy of consent form in the hospital notes (if recruited by secondary care)**
- **Send a copy of consent form to GP (if primary care or direct advert)**
- **Send a letter to GP with a copy of Patient Information Leaflet**
- **Put recruitment sticker on patient's notes along with a copy of the Patient Information Leaflet**

Please ensure the participant is given the following:

- **Diary**
- **Spare weekly questionnaires and envelopes**
- **Travel expenses**
- **Small gift**

Investigator's/designee's Signature: _____ Date D D / M M M / 2 0 Y Y

DD/MMM/YYYY

Participant initials: ☐☐☐	VISIT 2 – 2 Month Follow Up
Participant ID: ☐☐☐☐☐	

☐ **Mark if visit not done**	
VISIT INFORMATION	
Date of Visit:	☐☐/☐☐☐/☐☐☐☐ **DD/MMM/YYYY**

MEDICATIONS		
In the last 2 months roughly how often have emollients been used? (tick one only)	Never ☐ Sometimes ☐ Always ☐	Rarely ☐ Often ☐
In the last 2 months roughly how often have steroids or calcineuron inhibitors been used? (tick one only)	Never ☐ Sometimes ☐ Always ☐	Rarely ☐ Often ☐
In the last 2 months roughly how often have wet/dry wraps been used for their eczema? (tick one only) (this includes tubifast, itchopaste bandage)	None ☐ 5-10 times ☐	1-4 times ☐ >10 times ☐
Has the eczema treatment changed since the last clinic visit?	Yes ☐	No ☐
If yes, type of change	Escalation ☐ Reduction ☐	Neutral Change ☐ Unsure ☐
If Unsure, please specify	_____	

Participant initials: ☐☐☐

Participant ID: ☐☐☐☐☐

VISIT 2 – 2 Month Follow Up

☐ **Mark if not done**

THREE ITEM SEVERITY SCALE (TIS)

Criteria	**Score** (tick one only)
Erythema	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐
Oedema / papulation	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐
Excoriation	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐

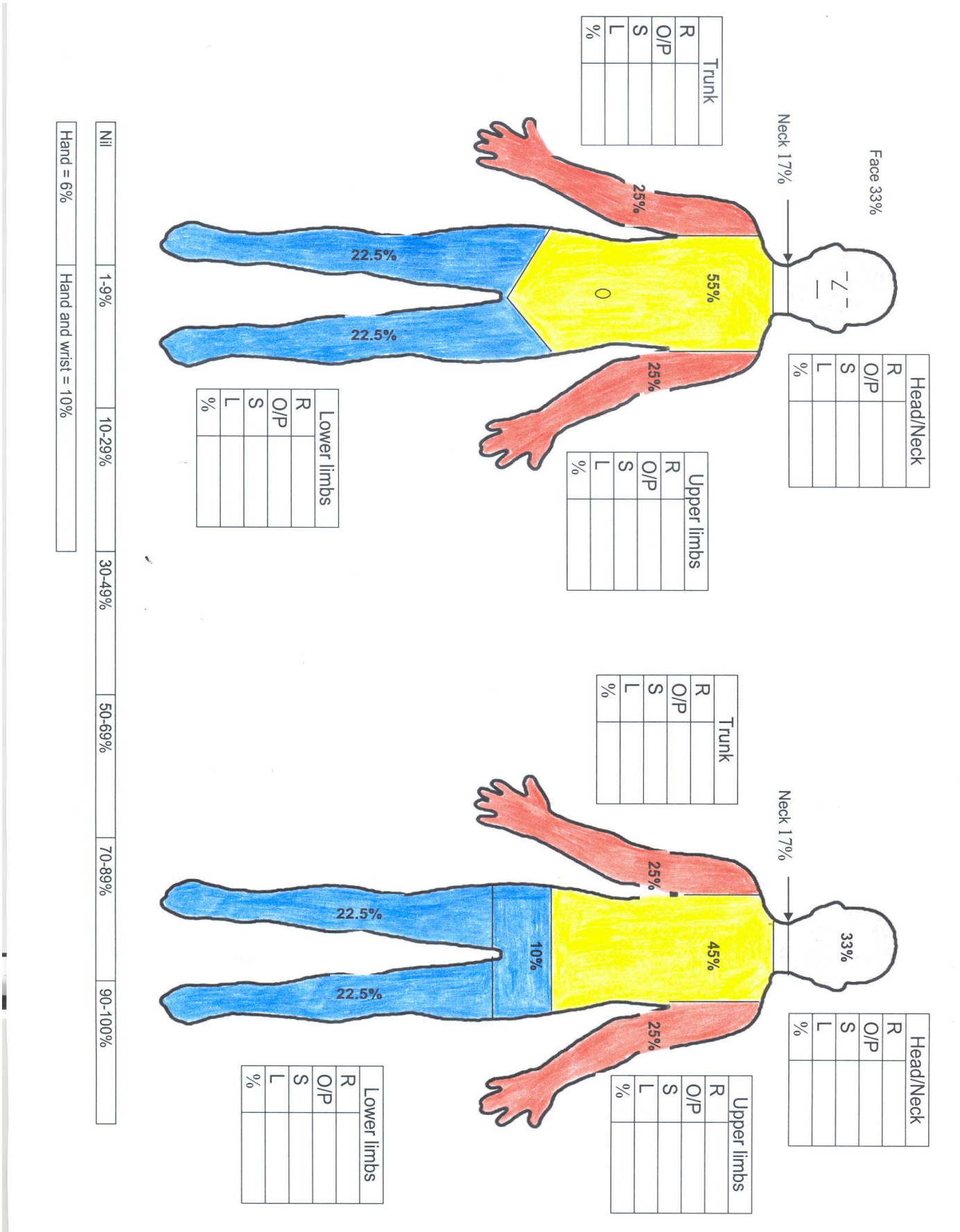
Representative Body Site: Choose one representative body site to assess all three signs. The representative site should be in an area covered by the clothing, and be the area that, in the view of the parent/participant, is most bothersome. The representative body site may change from visit to visit.

Total Score: ☐☐

Participant initials: | | | |

Participant ID: | | | | | |

VISIT 2 – 2 Month Follow Up



Participant initials: ☐☐☐ VISIT 2 – 2 Month Follow Up

Participant ID: ☐☐☐☐☐

☐ **Mark if not done**

- Assess each body area for **redness (erythema), papulation & oedema, scratching (excoriation) and lichenification (lined skin)**
- Using the photographic comparison table, assign a score for each of the signs in each of the four body areas. Assess each sign for the entire body region – so for example a patient may have grade 1 erythema in some areas, but grade 3 erythema in others. If that is the case, then the "average of the two" is taken and so the score become 2. Likewise, if they have some areas that are grade 2 and others that are grade 3, then the score becomes 2.5.
- Score the percentage area of each region affected by eczema

ECZEMA AREA AND SEVERITY INDEX (EASI)

Body Area	**% Area affected by Eczema** (tick one only)				**Criteria**	**Score** (tick one only)						
						Absent (0)	**(0.5)**	**Mild (1)**	**(1.5)**	**Moderate (2)**	**(2.5)**	**Severe (3)**
Head and Neck	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐
Upper Limbs	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐
Trunk	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐
Lower Limbs	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐

Participant initials: ☐☐☐	VISIT 2 – 2 Month Follow Up
Participant ID: ☐☐☐☐☐	

☐ **Mark if not done**

INVESTIGATOR'S GLOBAL ASSESSMENT (IGA)

How is the child's eczema <u>today</u>?

☐	☐	☐	☐	☐	☐
Clear	Almost clear	Mild	Moderate	Severe	Very severe

Please ensure Visit 2 Parent/Guardian/Child Questionnaires are completed during the visit:

	Tick when completed	Completed by: (tick one only)	
• **PATIENT'S GLOBAL ASSESSMENT (PGA) (included in 'Clinic Questions')** To be completed by parent/guardian or child Please request that where possible if the child performs the baseline assessment, the child completes the follow up questionnaires or if the parent/guardian performs the baseline assessment, the parent/guardian completes the follow up questionnaires.	☐	Parent/Guardian	☐
		Child	☐
• **PATIENT ORIENTED ECZEMA MEASURE (POEM)** To be completed by parent/guardian or child	☐	Parent/Guardian	☐
		Child	☐
• **CLINIC QUESTIONS** To be completed by parent/guardian or child	☐		

Participant initials: ☐☐☐	VISIT 2 – 2 Month Follow Up
Participant ID: ☐☐☐☐☐	

UNBLINDING	
Have you (nurse) become accidentally unblinded since last visit?	No ☐ Yes ☐
If yes, please briefly describe circumstances of unblinding.	_____ _____

NOT FOR DATABASE:

REMINDERS	
Please collect the diary from the parent/guardian/child and ensure it is fully completed prior to the parent/guardian/child leaving the clinic.	
• **Has the participant had any healthcare visits for eczema?** • **Has the participant been prescribed any topical treatment for eczema?** • **Has the participant had any skin infections?** • **Has the participant or parent/carer made any purchases for eczema?** • **Has the participant or parent/carer had any time off work and school due to eczema?**	Please use the data recorded in the diaries to complete the eCRF, any extra information that is gained through the clinic visit can be recorded on the pages at the end of the worksheet.
• **Please ensure the diary has been issued** • **Book an appointment for the next clinic visit** • **If consent has been obtained to collect a saliva sample and this has not been previously collected, has a sample been collected today and recorded in the CRF?** • **If any protocol deviations have taken place ensure this is recorded on the protocol deviation worksheet.**	

Investigator's/designee's Signature: _____ Date ☐☐/☐☐☐/**2 0**☐☐

DD/MMM/YYYY

Participant initials: ☐☐☐	VISIT 3 - 4 Month Follow Up
Participant ID: ☐☐☐☐☐	

☐ **Mark if visit not done**

VISIT INFORMATION

Date of Visit:	☐☐/☐☐☐/☐☐☐☐ **DD/MMM/YYYY**

MEDICATIONS

Has the eczema treatment changed since the last clinic visit?	Yes ☐	No ☐
If yes, type of change	Escalation ☐	Neutral Change ☐
	Reduction ☐	Unsure ☐
If Unsure, please specify	_____	

☐ **Mark if not done**

THREE ITEM SEVERITY SCALE (TIS)

Criteria	**Score** (tick one only)			
Erythema	Absent (0) ☐	Mild (1) ☐	Moderate (2) ☐	Severe (3) ☐
Oedema / papulation	Absent (0) ☐	Mild (1) ☐	Moderate (2) ☐	Severe (3) ☐
Excoriation	Absent (0) ☐	Mild (1) ☐	Moderate (2) ☐	Severe (3) ☐

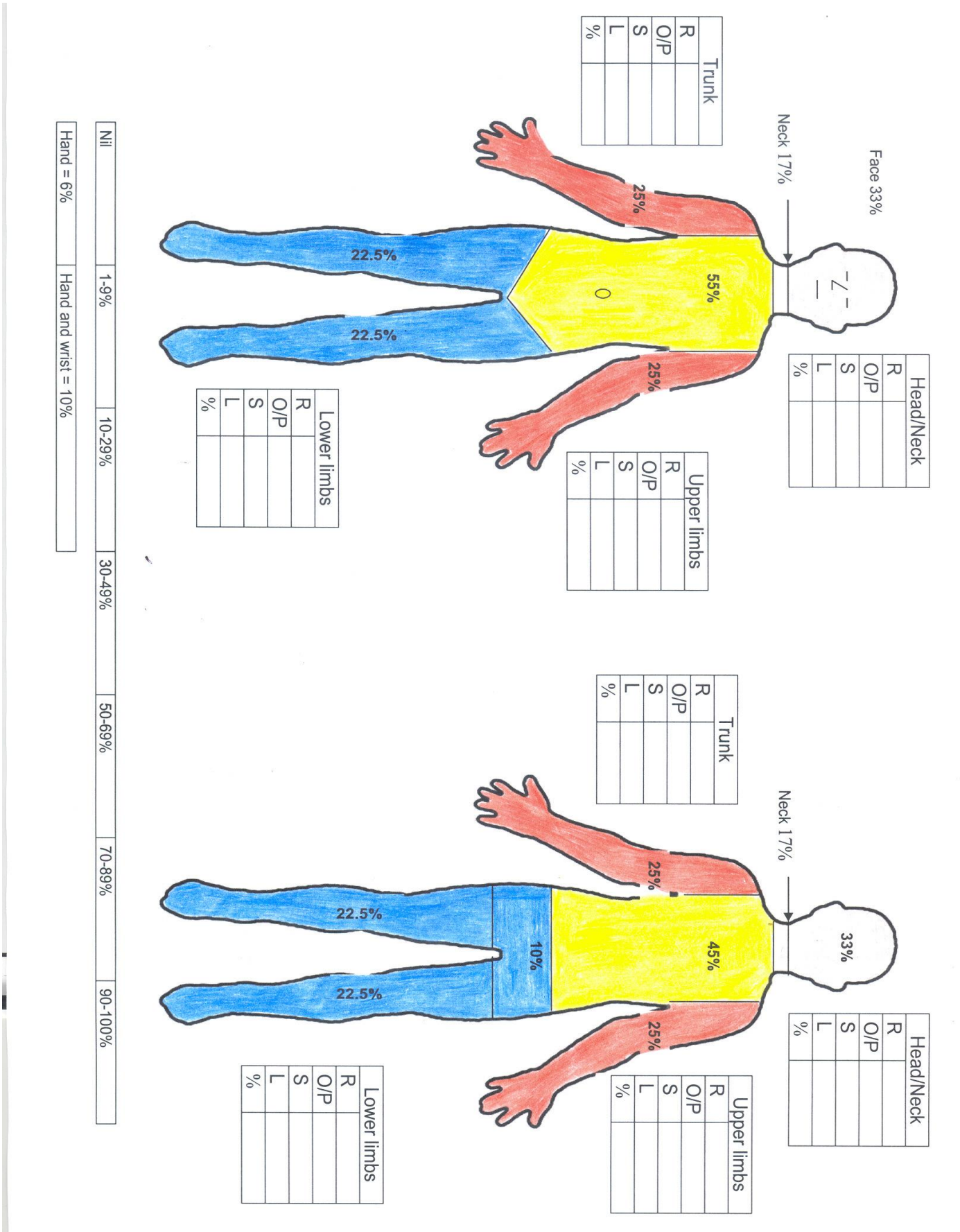
Representative Body Site: Choose one representative body site to assess all three signs. The representative site should be in an area covered by the clothing, and be the area that, in the view of the parent/participant, is most bothersome. The representative body site may change from visit to visit.

Total Score: ☐☐

Participant initials: | | | |

Participant ID: | | | | | |

VISIT 3 - 4 Month Follow Up



Participant initials: ☐☐☐ VISIT 3 - 4 Month Follow Up

Participant ID: ☐☐☐☐☐

☐ **Mark if not done**

- Assess each body area for **redness (erythema), papulation & oedema, scratching (excoriation) and lichenification (lined skin)**
- Using the photographic comparison table, assign a score for each of the signs in each of the four body areas. Assess each sign for the entire body region – so for example a patient may have grade 1 erythema in some areas, but grade 3 erythema in others. If that is the case, then the "average of the two" is taken and so the score become 2. Likewise, if they have some areas that are grade 2 and others that are grade 3, then the score becomes 2.5.
- Score the percentage area of each region affected by eczema

ECZEMA AREA AND SEVERITY INDEX (EASI)

Body Area	% Area affected by Eczema (tick one only)				Criteria	Score (tick one only)						
						Absent (0)	(0.5)	Mild (1)	(1.5)	Moderate (2)	(2.5)	Severe (3)
Head and Neck	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐
Upper Limbs	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐
Trunk	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐
Lower Limbs	Nil ☐	50-69% ☐			Redness	☐	☐	☐	☐	☐	☐	☐
	1-9% ☐	70-89% ☐			Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29% ☐	90-100% ☐			Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49% ☐				Lichenification	☐	☐	☐	☐	☐	☐	☐

Participant initials: ☐☐☐	VISIT 3 - 4 Month Follow Up
Participant ID: ☐☐☐☐☐	

☐ **Mark if not done**

INVESTIGATOR'S GLOBAL ASSESSMENT (IGA)

How is the child's eczema <u>today</u>?

☐	☐	☐	☐	☐	☐
Clear	Almost clear	Mild	Moderate	Severe	Very severe

Please ensure Visit 3 Parent/Guardian/Child Questionnaires are completed during the visit:

	Tick when completed	**Completed by: (tick one only)**	
• **PATIENT'S GLOBAL ASSESSMENT (PGA) (included in 'Clinic Questions')** To be completed by parent/guardian or child Please request that where possible if the child performs the baseline assessment, the child completes the follow up questionnaires or if the parent/guardian performs the baseline assessment, the parent/guardian completes the follow up questionnaires.	☐	Parent/Guardian	☐
		Child	☐
• **PATIENT ORIENTED ECZEMA MEASURE (POEM)** To be completed by parent/guardian or child	☐	Parent/Guardian	☐
		Child	☐
• **CLINIC QUESTIONS** To be completed by parent/guardian or child	☐		

Participant initials: ☐☐☐	VISIT 3 - 4 Month Follow Up
Participant ID: ☐☐☐☐☐	

UNBLINDING	
Have you (nurse) become accidentally unblinded since last visit?	No ☐ Yes ☐
If yes, please briefly describe circumstances of unblinding.	_____ _____

NOT FOR DATABASE:

REMINDERS

Please collect the diary from the parent/guardian/child and ensure it is fully completed prior to the parent/guardian/child leaving the clinic.

• **Has the participant had any healthcare visits for eczema?** • **Has the participant been prescribed any topical treatment for eczema?** • **Has the participant had any skin infections?** • **Has the participant or parent/care made any purchases for eczema?** • **Has the participant or parent/carer had any time off work and school due to eczema?**	Please use the data recorded in the diaries to complete the eCRF, any extra information that is gained through the clinic visit can be recorded on the pages at the end of the worksheet.

- **Please ensure the diary has been issued**
- **Book an appointment for the next clinic visit**
- **The parent who filled in the EQ-5D-3L at visit 1 was _____ (see page 17). Please request this same parent brings the child to the next visit, if possible, for questionnaire consistency.**
- **If consent has been obtained to collect a saliva sample and this has not been previously collected, has a sample been collected today and recorded in the CRF?**
- **If any protocol deviations have taken place ensure this is recorded on the protocol deviation worksheet.**

Investigator's/designee's Signature: _____ Date ☐☐/☐☐☐/**2 0**☐☐

DD/MMM/YYYY

Participant initials: ☐☐☐	VISIT 4 - 6 Month Follow Up
Participant ID: ☐☐☐☐☐	

☐ **Mark if visit not done**

VISIT INFORMATION

Date of Visit:	☐☐/☐☐☐/☐☐☐☐ **DD/MMM/YYYY**

HEIGHT

This should be entered onto the eCRF as soon as possible, even if the rest of the visit data is not entered until a later date

Height at this visit	☐☐☐ **cm**

ECZEMA TREATMENT

- **Please only record medications used on the areas covered by the clothing, not those used on hands/feet**
- **If more than 2 medications for each category have been used in the last month please enter the most frequently used medication**
- **Main emollient/steroid/calcineurin inhibitors = most frequently used**
- **Please see emollient ladder/steroid ladders for classification of consistency/potency**

EMOLLIENTS

Has the child used Emollients on the body within the last month? No ☐ Yes ☐

Name of Emollient used on body	Consistency (tick one only)	Main Emollient?
1. _____	Light ☐ Creamy ☐ Greasy ☐ Very Greasy ☐	Yes ☐ No ☐
2. _____	Light ☐ Creamy ☐ Greasy ☐ Very Greasy ☐	Yes ☐ No ☐

Please see Emollient ladder for classification of medications into Light, Creamy, Greasy and Very Greasy

TOPICAL STEROIDS

Has the child used topical steroids on the body within the last month? No ☐ Yes ☐

Name of Steroid used on body	Potency (tick one only)	Main Steroid?
1. _____	Mild ☐ Moderate ☐ Potent ☐ Very Potent ☐	Yes ☐ No ☐

Participant initials: ☐☐☐	VISIT 4 - 6 Month Follow Up
Participant ID: ☐☐☐☐☐	

2. _____	Mild ☐ Moderate ☐ Potent ☐ Very Potent ☐	Yes ☐ No ☐

Please see Steroid Ladder for classification of medications into Mild, Moderate, Potent or Very Potent.

CALCINEURIN INHIBITORS		
Has the child used Calcineurin Inhibitors on the body within the last month? (eg Protopic, Elidel) **No ☐ Yes ☐**		
Name of Calcinuerin Inhibitor used on body	**Strength** (tick one only)	**Main Calcineurin Inhibitor?**
1. _____	Mild ☐ Moderate ☐	Yes ☐ No ☐
2. _____	Mild ☐ Moderate ☐	Yes ☐ No ☐

Protopic (Tacrolimus) = 0.03% = Mild

Elidel (Pimecrolimus) = 1% = Moderate

MEDICATIONS		
Has the eczema treatment changed since the last clinic visit?	Yes ☐	No ☐
If yes, type of change	Escalation ☐	Neutral Change ☐
	Reduction ☐	Unsure ☐
If Unsure, please specify	_____	

SKIN INFECTIONS	
If infection is suspected this should be followed up after the visit and added to the infections log if necessary.	
Does the skin appear infected at this visit?	No ☐ Yes ☐

Participant initials: ☐☐☐

Participant ID: ☐☐☐☐☐

VISIT 4 - 6 Month Follow Up

☐ **Mark if not done**

THREE ITEM SEVERITY SCALE (TIS)

Criteria	**Score** (tick one only)
Erythema	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐
Oedema / papulation	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐
Excoriation	Absent (0) ☐ Mild (1) ☐ Moderate (2) ☐ Severe (3) ☐

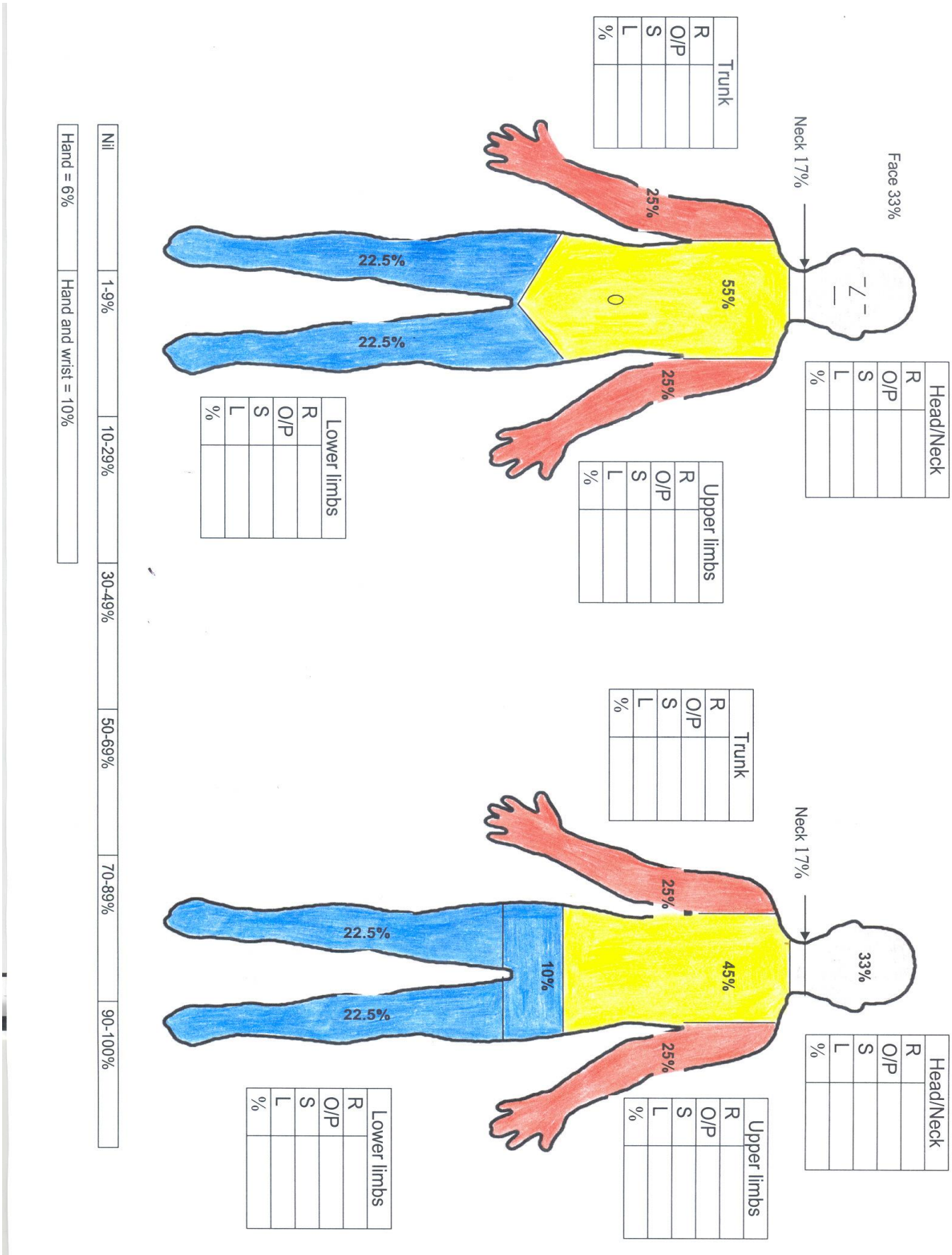
Representative Body Site: Choose one representative body site to assess all three signs. The representative site should be in an area covered by the clothing, and be the area that, in the view of the parent/participant, is most bothersome. The representative body site may change from visit to visit.

Total Score: ☐☐

Participant initials: | | | |

Participant ID: | | | | | |

VISIT 4 - 6 Month Follow Up



Participant initials: ☐☐☐

Participant ID: ☐☐☐☐☐

VISIT 4 - 6 Month Follow Up

☐ **Mark if not done**

- Assess each body area for redness (erythema), papulation & oedema, scratching (excoriation) and lichenification (lined skin)
- Using the photographic comparison table, assign a score for each of the signs in each of the four body areas. Assess each sign for the entire body region – so for example a patient may have grade 1 erythema in some areas, but grade 3 erythema in others. If that is the case, then the "average of the two" is taken and so the score become 2. Likewise, if they have some areas that are grade 2 and others that are grade 3, then the score becomes 2.5.
- Score the percentage area of each region affected by eczema

ECZEMA AREA AND SEVERITY INDEX (EASI)

Body Area	**% Area affected by Eczema** (tick one only)				**Criteria**	**Score** (tick one only)						
						Absent (0)	**(0.5)**	**Mild (1)**	**(1.5)**	**Moderate (2)**	**(2.5)**	**Severe (3)**
Head and Neck	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐
Upper Limbs	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐
Trunk	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐
Lower Limbs	Nil	☐	50-69%	☐	Redness	☐	☐	☐	☐	☐	☐	☐
	1-9%	☐	70-89%	☐	Oedema/Papulation	☐	☐	☐	☐	☐	☐	☐
	10-29%	☐	90-100%	☐	Scratching	☐	☐	☐	☐	☐	☐	☐
	30-49%	☐			Lichenification	☐	☐	☐	☐	☐	☐	☐

Participant initials: ☐☐☐	VISIT 4 - 6 Month Follow Up
Participant ID: ☐☐☐☐☐	

HYPERLINEAR PALMS			
Hyperlinear palms?	No ☐	Yes ☐	Unsure ☐

Please see Trial Manual for details

☐ **Mark if not done**

INVESTIGATOR'S GLOBAL ASSESSMENT (IGA)

How is the child's eczema <u>today</u>?

☐	☐	☐	☐	☐	☐
Clear	Almost clear	Mild	Moderate	Severe	Very severe

Please ensure Visit 4 Parent/Guardian/Child Questionnaires are completed during the visit:

	Tick when completed	**Completed by: (tick one only)**	
• **PATIENT'S GLOBAL ASSESSMENT (PGA) (included in 'Clinic Questions')** To be completed by parent/guardian or child	☐	Parent/Guardian	☐
		Child	☐
• **PATIENT ORIENTED ECZEMA MEASURE (POEM)** To be completed by parent/guardian or child	☐	Parent/Guardian	☐
		Child	☐
• **CLINIC QUESTIONS** To be completed by parent/guardian or child	☐		
• **DERMATITIS FAMILY IMPACT QUESTIONNAIRE (DFI)** To be completed by parent/guardian	☐		
• **EQ-5D-3L** To be completed by parent/guardian	☐		
• **THE CHILD HEALTH UTILITY 9 DIMENSIONS (CHU-9D)** To be completed by parent/guardian or child <u>for children of aged 5 or over only</u>	☐		
• **ADQoL** To be completed by parent/guardian or child	☐		
Comments on ADQoL:			

Participant initials: ☐☐☐	Visit 4 - 6 Month Follow Up
Participant ID: ☐☐☐☐☐	

UNBLINDING	
Have you (nurse) become accidentally unblinded since last visit?	No ☐ Yes ☐
If yes, please briefly describe circumstances of unblinding.	_____ _____

NOT FOR DATABASE:

REMINDERS	
Please collect the diary from the parent/guardian/child and ensure it is fully completed prior to the parent/guardian/child leaving the clinic.	
• **Has the participant had any healthcare visits for eczema?** • **Has the participant been prescribed any topical treatment for eczema?** • **Has the participant had any skin infections?** • **Has the participant or parent/carer made any purchases for eczema?** • **Has the participant or parent/carer had any time off work and school due to eczema?**	Please use the data recorded in the diaries to complete the eCRF, any extra information that is gained through the clinic visit can be recorded on the pages at the end of the worksheet.
• **If consent has been obtained to collect a saliva sample and this has not been previously collected, has a sample been collected today and recorded in the CRF?** • **If any protocol deviations have taken place ensure this is recorded on the protocol deviation worksheet.**	

Investigator's/designee's Signature: _____ Date ☐☐/☐☐☐/**2**☐☐☐
DD/MMM/YYYY

Participant initials: ☐☐☐	END OF TRIAL
Participant ID: ☐☐☐☐☐	For database: 777

To be completed when the participant reaches their 6 month visit or if they choose to withdraw from the trial completely.

END OF TRIAL	
Has the participant completed the 6 month clinic visit?	No ☐ Yes ☐
If No, date of withdrawal:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
Participant Status: If No, check the primary reason for Discontinuation *(tick one box):*	Death ☐ Withdrawal of Consent ☐ Withdrawal of Consent due to Adverse Event ☐ Lost to Follow Up ☐ Trial terminated by sponsor ☐ Other ☐ If Withdrawal of Consent or other, please specify _____

Investigator's/designee's Signature: _____ Date ☐☐/☐☐☐/**2 0**☐☐
DD/MMM/YYYY

Participant initials: ☐☐☐	SUMMARY INFORMATION: SAMPLE COLLECTION
Participant ID: ☐☐☐☐☐	

A sample should only be collected if consent was obtained for the genetic substudy.

SAMPLE COLLECTION				
	Was sample collected?		**Date of assessment** DD/MMM/YYYY	**If No, please give reason**
	No	**Yes**		
Saliva sample	☐	☐	D D M M M Y Y Y Y	

Participant initials: ☐☐☐ **Participant ID:** ☐☐☐☐☐	SUMMARY INFORMATION: HEALTHCARE VISITS FOR ECZEMA

Pages 40-44 can be used to record any information collected during the clinic visit, it is not necessary to transcribe all information from the diary to these pages. The diary data can be entered directly into the eCRF.

HEALTHCARE VISITS FOR ECZEMA

Has the participant had any healthcare visits for eczema? No ☐ Yes ☐

No.	Date of Visit	Tick if estimated	Type of visit 1= GP, 2 = Practice Nurse, 3 = Outpatients, 4= Inpatient, 5 = Other (If Other, specify)	Number of nights in hospital
1	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
2	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
3	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
4	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
5	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
6	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
7	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
8	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
9	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
10	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
11	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
12	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
13	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
14	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
15	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
16	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
17	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
18	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
19	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐
20	D D M M M 2 0 Y Y	☐	☐ ----------	☐☐

Participant initials: | | | |

Participant ID: | | | | | |

SUMMARY INFORMATION: ECZEMA PRESCRIPTIONS

Pages 40-44 can be used to record any information collected during the clinic visit, it is not necessary to transcribe all information from the diary to these pages. The diary data can be entered directly into the eCRF.

Please have the parent detail all prescriptions, even if repeat prescriptions

ECZEMA PRESCRIPTIONS

Has the participant been prescribed any treatment for their eczema? No ☐ Yes ☐

No.	Date of Prescription	Tick if estimated	What was Prescribed?	Details (size/amount)
1	D D M M M 2 0 Y Y	☐		
2	D D M M M 2 0 Y Y	☐		
3	D D M M M 2 0 Y Y	☐		
4	D D M M M 2 0 Y Y	☐		
5	D D M M M 2 0 Y Y	☐		
6	D D M M M 2 0 Y Y	☐		
7	D D M M M 2 0 Y Y	☐		
8	D D M M M 2 0 Y Y	☐		
9	D D M M M 2 0 Y Y	☐		
10	D D M M M 2 0 Y Y	☐		
11	D D M M M 2 0 Y Y	☐		
12	D D M M M 2 0 Y Y	☐		
13	D D M M M 2 0 Y Y	☐		
14	D D M M M 2 0 Y Y	☐		
15	D D M M M 2 0 Y Y	☐		
16	D D M M M 2 0 Y Y	☐		
17	D D M M M 2 0 Y Y	☐		
18	D D M M M 2 0 Y Y	☐		
19	D D M M M 2 0 Y Y	☐		
20	D D M M M 2 0 Y Y	☐		

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SKIN INFECTIONS

Has the participant had any skin infections which required treatment with antibiotics or antivirals? No ☐ Yes ☐

No.	Start date of Skin Infection									Tick if estimated
1	D	D	M	M	M	2	0	Y	Y	☐
2	D	D	M	M	M	2	0	Y	Y	☐
3	D	D	M	M	M	2	0	Y	Y	☐
4	D	D	M	M	M	2	0	Y	Y	☐
5	D	D	M	M	M	2	0	Y	Y	☐
6	D	D	M	M	M	2	0	Y	Y	☐
7	D	D	M	M	M	2	0	Y	Y	☐
8	D	D	M	M	M	2	0	Y	Y	☐
9	D	D	M	M	M	2	0	Y	Y	☐
10	D	D	M	M	M	2	0	Y	Y	☐
11	D	D	M	M	M	2	0	Y	Y	☐
12	D	D	M	M	M	2	0	Y	Y	☐
13	D	D	M	M	M	2	0	Y	Y	☐
14	D	D	M	M	M	2	0	Y	Y	☐
15	D	D	M	M	M	2	0	Y	Y	☐
16	D	D	M	M	M	2	0	Y	Y	☐

The start date of the infection should be considered as the date of the prescription.

Participant initials: ☐☐☐ **Participant ID:** ☐☐☐☐☐	SUMMARY INFORMATION: PURCHASES FOR ECZEMA

Pages 40-44 can be used to record any information collected during the clinic visit, it is not necessary to transcribe all information from the diary to these pages. The diary data can be entered directly into the eCRF.

PURCHASES FOR ECZEMA

Has the participant or parent/carer made any purchases or incurred any out of pocket expenses as a result of eczema? No ☐ Yes ☐

No.	Date of Purchase	Tick if estimated	Item Bought	Cost ££:pp	Estimated cost if you didn't need to buy a specialist item
1	D D M M M 2 0 Y Y	☐			
2	D D M M M 2 0 Y Y	☐			
3	D D M M M 2 0 Y Y	☐			
4	D D M M M 2 0 Y Y	☐			
5	D D M M M 2 0 Y Y	☐			
6	D D M M M 2 0 Y Y	☐			
7	D D M M M 2 0 Y Y	☐			
8	D D M M M 2 0 Y Y	☐			
9	D D M M M 2 0 Y Y	☐			
10	D D M M M 2 0 Y Y	☐			
11	D D M M M 2 0 Y Y	☐			
12	D D M M M 2 0 Y Y	☐			
13	D D M M M 2 0 Y Y	☐			
14	D D M M M 2 0 Y Y	☐			
15	D D M M M 2 0 Y Y	☐			
16	D D M M M 2 0 Y Y	☐			
17	D D M M M 2 0 Y Y	☐			
18	D D M M M 2 0 Y Y	☐			
19	D D M M M 2 0 Y Y	☐			
20	D D M M M 2 0 Y Y	☐			

Pages 40-44 can be used to record any information collected during the clinic visit, it is not necessary to transcribe all information from the diary to these pages. The diary data can be entered directly into the eCRF.

TIME OFF WORK AND SCHOOL DUE TO ECZEMA

Has the participant or parent/carer had any time off work and school due to eczema? No ☐ Yes ☐

No.	Date started	Tick if estimated	Time off school/nursery HH:MM	Parental/carer time off from paid employment HH:MM	Reason
1	D D M M M 2 0 Y Y	☐			
2	D D M M M 2 0 Y Y	☐			
3	D D M M M 2 0 Y Y	☐			
4	D D M M M 2 0 Y Y	☐			
5	D D M M M 2 0 Y Y	☐			
6	D D M M M 2 0 Y Y	☐			
7	D D M M M 2 0 Y Y	☐			
8	D D M M M 2 0 Y Y	☐			
9	D D M M M 2 0 Y Y	☐			
10	D D M M M 2 0 Y Y	☐			
11	D D M M M 2 0 Y Y	☐			
12	D D M M M 2 0 Y Y	☐			
13	D D M M M 2 0 Y Y	☐			
14	D D M M M 2 0 Y Y	☐			
15	D D M M M 2 0 Y Y	☐			
16	D D M M M 2 0 Y Y	☐			
17	D D M M M 2 0 Y Y	☐			
18	D D M M M 2 0 Y Y	☐			
19	D D M M M 2 0 Y Y	☐			
20	D D M M M 2 0 Y Y	☐			

PROTOCOL DEVIATIONS

Any Protocol Deviations to report? **No** ☐ **Yes** ☐

No.	Deviation (enter code as below)	Date of deviation	Tick if estimated	Comments
1		D D M M M 2 0 Y Y	☐	
2		D D M M M 2 0 Y Y	☐	
3		D D M M M 2 0 Y Y	☐	
4		D D M M M 2 0 Y Y	☐	
5		D D M M M 2 0 Y Y	☐	
6		D D M M M 2 0 Y Y	☐	
7		D D M M M 2 0 Y Y	☐	
8		D D M M M 2 0 Y Y	☐	
9		D D M M M 2 0 Y Y	☐	
10		D D M M M 2 0 Y Y	☐	

(Record multiple reasons on separate lines) **CODES**

1= Inclusion / Exclusion Criteria Deviation, 2= Trial procedure not performed per protocol 3= Informed Consent Deviation
4= Subject Non-Compliance with Protocol 5= Treatment Randomisation Error 6= Other (specify in comments)