PATIENT PATHWAY

Patient sticker

______________________________

Study specific number (order of enrolment) ______

Previous conventional PDT? ______

Date of enrolment ______

Consent signed (tick) ______

Randomisation* (record below in treatment section) (tick) ______

* Patients will be randomised to have right side (patient’s right hand side)
treated first or left side based on selection of card from envelope.

Procedure
1. Define two symmetrical treatment fields
2. Mark boundaries using plastic template (10 x 7cm) and skin marking pen
3. Mark left and right (L & R) on scalp
4. Photograph*
5. Count AKs (in team of two conferring) and mark with skin marking pen
6. Photograph scalp with markings
7. Make polythene map by marking over each previously marked AK and the
   outline of template. Mark with surface landmarks for purpose of locating
treatment site at follow up.
8. Photograph polythene map
9. Store polythene sheet in patient specific section of Lever arch folder
10. Document attendance in medical record
11. Give patient GP letter

* Each set of photos should include lateral right, lateral left and straight
   on (pre and post marking). In each photo the patient specific study
   number (number in which they are enrolled) should be visible within the
   shot and an indication of left and right.

RECORDS:

Size of template used ______

Total AK’s on patients right hand side ______

Total AK’s on patients left hand side ______

Version 6 April 29th 2014
DATE AND TIME FOR TREATMENT NEXT WEEK  ___________  ______

1 Daylight treatment– start process approx. at 10 am, cream on at 10.30 am and patient to be outdoors from 11 am to 1 pm

ADVISE PATIENT TO BRING WARM CLOTHES TO WRAP UP OUTDOORS FOR DAYLIGHT TREATMENT SESSION

Notes:
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________

DAYLIGHT TREATMENT SESSION

Date and Time  ___________  ______

Side to be treated (patient’s side) __________

1. Mark out boundaries of area to be treated
2. Apply P20 to all of exposed skin and allow to dry for approx. 30 minutes
3. Apply mepore to NON treatment side, use midline from nose as boundary (this mepore to prevent transfer of the MAL cream)
4. Apply 1-2 gram of MAL to the treatment field
5. Record fluorescence with Wood’s lights prior to light exposure (record below)
6. Within 30 minutes patient is to be positioned outdoors* (optimal time for patient to go to toilet if needed).
7. (VAS) (1-100) at 1, 30, 60, 90 and 120 minutes by nurses (record below). Stopwatch held by nurse to be used to ensure timing intervals. Patient not to be aware of value.
8. Nurses to enquire at each VAS scoring interval if there has been any interruption to treatment.
9. If treatment discontinued because of pain the timing of this will be recorded
10. Any adverse event is to be recorded
11. Treatment is completed after two hours of exposure (both for daylight and theatre light)
12. Remove remaining cream on scalp
13. Patient can be instructed to spend the rest of the day as they normally would – i.e. no restriction on normal outdoor behaviour or attire

Version 6 April 29th 2014
DAYLIGHT TREATMENT RECORDS

Pre-exposure Wood’s light fluorescence  ________________

VAS score at;

1 minute __________

Notes:

30 minutes __________
Any interruption in prior 30 minutes

60 minutes __________
Any interruption in prior 30 minutes

90 minutes __________
Any interruption in prior 30 minutes

120 minutes __________
Any interruption in prior 30 minutes

TOTAL EXPOSURE TIME __________

If less than 2 hours – reason:

Version 6 April 29th 2014
Total duration of interruptions: ___________

General notes on daylight PDT session:

BEFORE PATIENT LEAVES POST TREATMENT

- ENSURE THEY HAVE APPOINTMENT TO BE SEEN THE FOLLOWING DAY FOR REVIEW AND ONE WEEK AFTER INITIAL TREATMENT TO HAVE SECOND SIDE TREATED

REVIEW FOR TOLERABILITY POST DAYLIGHT TX

Date and Time: ________________

Local effects;

Erythema (mild/mod/severe) ________

Erosions (mild/mod/severe) ________

How long pain persisted ____________

Overall tolerability (10 –very tolerable, 0 intolerable) ____

General notes/Adverse reactions:

Painkillers required

Version 6 April 29th 2014
How much sun exposure during remainder of day after treatment

_____________________________________________________________________________________

_____________________________________________________________________________________

_____________________________________________________________________________________

If patient had prior conventional PDT how do they compare?

_____________________________________________________________________________________

_____________________________________________________________________________________

_____________________________________________________________________________________

Rank PDT modalities experienced so far (daylight/theatre lamp/conventional)?

_____________________________________________________________________________________

_____________________________________________________________________________________

_____________________________________________________________________________________

Photograph (as at initial enrolment) Tick _____
Documented visit in medical record Tick____

THEATRE LIGHT TREATMENT SESSION

Date and Time ________________ __________

Side to be treated (patient’s side) __________

1. Apply mepore to NON treatment side, use midline from nose as boundary (this mepore to prevent transfer of the MAL cream)
2. Apply 1-2 gram of MAL to the treatment field
3. Record fluorescence with Wood’s lights prior to light exposure (record below)
4. Within 30 minutes patient is to be positioned under theatre light\(^1\) (optimal time for patient to go to toilet if needed).
5. (VAS) (1-100) at 1, 30, 60, 90 and 120 minutes by nurses (record below).
   Stopwatch held by nurse to be used to ensure timing intervals. Patient not to be aware of value.
6. Nurses to enquire at each VAS scoring interval if there has been any interruption to treatment.
7. If treatment discontinued because of pain the timing of this will be recorded
8. Any adverse event is to be recorded
9. Treatment is completed after two hours of exposure
10. Remove remaining cream on scalp
11. Patient can be instructed to spend the rest of the day as they normally would – i.e. no restriction on normal outdoor behaviour or attire

Version 6 April 29\(^{th}\) 2014
Patients to be positioned under theatre light with pillow under back and radio on in room. In theatre room patient to be given the call button and advised to call for assistance rather than leaving the room. Patient to have goggles (as used in phototherapy).

THEATRE LIGHT TREATMENT RECORDS

<table>
<thead>
<tr>
<th>St Vincent’s University Hospital Dermatology Department PDT Treatment Record Sheet for PWD500 Theatre Light</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Initials:</strong> __________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Theatre Light Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Site: ______________</td>
<td>*Intensity Setting: 10 (i.e. all at full intensity) LED</td>
</tr>
<tr>
<td>Lesion Size: ______________</td>
<td>Measured Output: ________ mW/cm² at start</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRE-TREATMENT CHECKS</th>
<th>CHECK COMPLETE</th>
<th>INITIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient consent form completed and sighed</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Patient triple ID check performed</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Patient advised not to move head much during treatment</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Head rest positioned on patient chair</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Blinds drawn and lights switched off in treatment room</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Appropriate eyewear issued to patient: Front &amp; Side: Visor plus Shade 5 Glasses Back: Visor only and staff: Shade 3 glasses</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Light switched on and set to intensity setting 10 (5 bright led)</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Light positioned at 65 cm from patient’s head</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Light centred on treatment site using template</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Output measured with black PDT meter greater than 45 mW/cm²</td>
<td>[ ]</td>
<td>______</td>
</tr>
<tr>
<td>Treatment countdown started on both stopwatches</td>
<td>[ ]</td>
<td>______</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>POST-TREATMENT CHECKS</th>
<th>CHECK COMPLETE</th>
<th>INITIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment time recorded</td>
<td>[ ]</td>
<td>______</td>
</tr>
</tbody>
</table>

ADDITIONAL INFORMATION/NOTES

Version 6 April 29th 2014
Pre-exposure Wood’s light fluorescence  ________________

Notes:

____________________________
____________________________
____________________________
____________________________
____________________________
____________________________
____________________________
____________________________

30 minutes ________
Any interruption in prior 30 minutes

____________________________
____________________________
____________________________
____________________________

60 minutes ________
Any interruption in prior 30 minutes

____________________________
____________________________
____________________________
____________________________

90 minutes ________
Any interruption in prior 30 minutes

____________________________
____________________________
____________________________
____________________________

120 minutes ________
Any interruption in prior 30 minutes

____________________________
____________________________
____________________________
____________________________

Version 6 April 29th 2014
TOTAL EXPOSURE TIME

If less than 2 hours – reason:
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

Total duration of interruptions

BEFORE PATIENT LEAVES POST TREATMENT

- ENSURE THEY HAVE APPOINTMENT TO BE SEEN THE FOLLOWING DAY FOR REVIEW

REVIEW FOR TOLERABILITY POST THEATRE LIGHT TX

Date and Time: _______________ _______________

Local effects;

Erythema (mild/mod/severe) _______

Erosions (mild/mod/severe) _______

How long pain persisted _______

Overall tolerability (10 – very tolerable, 0 intolerable) _____

Preference between two treatment modalities (daylight and theatre lamp)
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

General notes/Adverse reactions:
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

Version 6 April 29th 2014
Painkillers required

How much sun exposure during remainder of day after treatment

Rank PDT modalities experienced so far (daylight/theatre lamp/conventional)?

Photograph (as at initial enrolment) Tick
Documented visit in medical record Tick

BEFORE PATIENT LEAVES POST 2nd REVIEW

- ENSURE THEY HAVE APPOINTMENT TO BE SEEN approx. 28 DAYS LATER (ON A FRIDAY) FOR CLINICAL EFFICACY REVIEW

DATE FOR 28 DAY CLINICAL REVIEW __________

For each clinical review:

We will repeat procedure done at time of initial enrolment (see above) including making new map but also
We will use the baseline map and categorize response for AK lesions as complete response or non-complete response.

28-DAY CLINICAL EFFICACY REVIEW

DATE and TIME: ____________________

FOLLOW STEP-BY-STEP PROCESS OUTLINED IN ENROLMENT SECTION

Map made (in red ink) (tick) __
Photos taken (tick) ___

RIGHT HAND SIDE

Version 6 April 29th 2014
Total AK’s on patients right hand side _____

Number of AK’s on right hand side with complete response ______

Number of AK’s on right hand side with partial response ______

Number of new AK’s on right hand side ______

LEFT HAND SIDE

Total AK’s on patients left hand side _____

Number of AK’s on left side with complete response ______

Number of AK’s on left side with partial response ______

Number of new AK’s on left side ______

Notes:

_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________

DATE FOR 3 MONTH CLINICAL REVIEW __________ __________

3-MONTH CLINICAL EFFICACY REVIEW

DATE and TIME: ______________ __________

FOLLOW STEP-BY-STEP PROCESS OUTLINED IN ENROLMENT SECTION

Map made (in red ink) (tick) ___

Photos taken (tick) ___

RIGHT HAND SIDE

Total AK’s on patients right hand side _____

Number of AK’s on right hand side with complete response ______

Number of AK’s on right hand side with partial response ______
<table>
<thead>
<tr>
<th>Number of new AK's on right hand side ________</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFT HAND SIDE</td>
</tr>
<tr>
<td>Total AK's on patients left hand side _____</td>
</tr>
<tr>
<td>Number of AK's on left side with complete response ________</td>
</tr>
<tr>
<td>Number of AK's on left side with partial response ________</td>
</tr>
<tr>
<td>Number of new AK's on left side ________</td>
</tr>
<tr>
<td>Notes:</td>
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<tr>
<td></td>
</tr>
<tr>
<td>DATE FOR 6 MONTH CLINICAL REVIEW ____________</td>
</tr>
</tbody>
</table>

6 MONTH CLINICAL EFFICACY REVIEW
DATE and TIME: ____________________ ___________

FOLLOW STEP-BY-STEP PROCESS OUTLINED IN ENROLMENT SECTION
Map made (in red ink) (tick) ___
Photos taken (tick) ___

RIGHT HAND SIDE
Total AK’s on patients right hand side _____
Number of AK’s on right hand side with complete response ________
Number of AK’s on right hand side with partial response ________
Number of new AK’s on right hand side ________

LEFT HAND SIDE

Version 6 April 29th 2014
Total AK’s on patients left hand side ______

Number of AK’s on left side with complete response ______

Number of AK’s on left side with partial response ______

Number of new AK's on left side ______

Notes:

_____________________________________________________________________________________________

_____________________________________________________________________________________________

_____________________________________________________________________________________________

_____________________________________________________________________________________________

_____________________________________________________________________________________________

DATE FOR 9 MONTH CLINICAL REVIEW __________ ________

9 MONTH CLINICAL EFFICACY REVIEW

DATE and TIME: ____________________ ___________

FOLLOW STEP-BY-STEP PROCESS OUTLINED IN ENROLMENT SECTION

Map made (in red ink) (tick) __

Photos taken (tick) ___

RIGHT HAND SIDE

Total AK’s on patients right hand side _____

Number of AK’s on right hand side with complete response ______

Number of AK’s on right hand side with partial response ______

Number of new AK's on right hand side ______

LEFT HAND SIDE

Total AK’s on patients left hand side _____

Number of AK’s on left side with complete response ______

Number of AK’s on left side with partial response ______
Number of new AK's on left side ______

Notes:

_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________

DATE FOR 12 MONTH CLINICAL REVIEW __________  ______

12 MONTH CLINICAL EFFICACY REVIEW

DATE and TIME: ____________________ ___________

FOLLOW STEP-BY-STEP PROCESS OUTLINED IN ENROLMENT SECTION

Map made (in red ink) (tick) ___

Photos taken (tick) ___

RIGHT HAND SIDE

Total AK's on patients right hand side ______
Number of AK's on right hand side with complete response ______
Number of AK's on right hand side with partial response ______
Number of new AK's on right hand side ______

LEFT HAND SIDE

Total AK's on patients left hand side ______
Number of AK's on left side with complete response ______
Number of AK's on left side with partial response ______
Number of new AK's on left side ______

Notes:

_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________

Version 6 April 29th 2014