



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: subjid- _____ Alpha Code: alpha_code Visit # mevisit

NOTE: To be completed by the study team by direct examination of the subject at the 6 and 12 Month Follow-up Visits.

1. Date of examination: medtc

___ / ___ / ___
Day Month Year

2. Visual Acuity: (check one box for each eye)

	Right Eye <u>mevisual_r</u>	Left Eye <u>mevisual_l</u>
Measurable on Chart	<input type="checkbox"/> ₁ logMAR = ___ . ___ <u>meva_r</u>	<input type="checkbox"/> ₁ logMAR = ___ . ___ <u>meva_l</u>
Count Fingers	<input type="checkbox"/> ₂	<input type="checkbox"/> ₂
Hand Motions	<input type="checkbox"/> ₃	<input type="checkbox"/> ₃
Light Perception Only	<input type="checkbox"/> ₄	<input type="checkbox"/> ₄
No Light Perception	<input type="checkbox"/> ₅	<input type="checkbox"/> ₅

3. Intraocular Pressure (IOP)
Measurements:

- Measure IOP 3 times in each eye.

Right Eye (OD)

- a) ☐ Not measurable (skip meiopnm_r to question #4A)
- b) ___ mmHg meiop1_r
- c) ___ mm Hg meiop2_r
- d) ___ mmHg meiop3_r

Left Eye (OS)

- a) ☐ Not measurable (skip meiopnm_l to question #4A)
- b) ___ mmHg meiop1_l
- c) ___ mm Hg meiop2_l
- d) ___ mmHg meiop3_l

4A. Ocular Surface Discharge **Right Eye:** (Check all that apply)

	Yes	No
Serous (watery) <u>meserous_r</u>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
Purulent (yellowish, thick) <u>mepurulent_r</u>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
Foamy (foam-like) <u>mefoamy_r</u>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀

**FLuorometholone as Adjunctive MEdical Therapy for TT Surgery
(FLAME) Trial**

ME (009.2)
10/12/2021
Page 2 of 15



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

4B. Ocular Surface Discharge Left Eye: (Check all that apply)

		Yes	No
Serous (watery)	meserous_I	<input type="checkbox"/> _1	<input type="checkbox"/> _0
Purulent (yellowish, thick)	mepurulent_I	<input type="checkbox"/> _1	<input type="checkbox"/> _0
Foamy (foam-like)	mefoamy_I	<input type="checkbox"/> _1	<input type="checkbox"/> _0

5A. Assessment of Trichiasis Right Eye:

		# Upper Lid	# Lower Lid
a.	Number of lashes whose point touches the cornea	mecornea_rul	mecornea_rll
b.	Number of lashes whose point touches the globe medial to the cornea	memedial_rul	memedial_rll
c.	Number of lashes whose point touches the globe lateral to the cornea	melateral_rul	melateral_rll

5B. Assessment of Trichiasis Left Eye:

		# Upper Lid	# Lower Lid
a.	Number of lashes whose point touches the cornea	mecornea_lul	mecornea_lll
b.	Number of lashes whose point touches the globe medial to the cornea	memedial_lul	memedial_lll
c.	Number of lashes whose point touches the globe lateral to the cornea	melateral_lul	melateral_lll



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

6. Trichiasis Grading:	Right Eye		Left Eye	
	<i>metrich_rul</i> Upper Lid	<i>metrich_rll</i> Lower Lid	<i>metrich_lul</i> Upper Lid	<i>metrich_lll</i> Lower Lid
T0: No Trichiasis	<input type="checkbox"/> _0	<input type="checkbox"/> _0	<input type="checkbox"/> _0	<input type="checkbox"/> _0
T1: Lashes deviated toward the eye, but not touching the globe	<input type="checkbox"/> _1	<input type="checkbox"/> _1	<input type="checkbox"/> _1	<input type="checkbox"/> _1
T2: Lashes touching the globe but not rubbing the cornea	<input type="checkbox"/> _2	<input type="checkbox"/> _2	<input type="checkbox"/> _2	<input type="checkbox"/> _2
T3: Lashes constantly rubbing the cornea	<input type="checkbox"/> _3	<input type="checkbox"/> _3	<input type="checkbox"/> _3	<input type="checkbox"/> _3

7. Evidence/extent of epilation (Broken/regrowing lashes or sections of eyelid denuded of lashes):	Right Eye		Left Eye	
	<i>meepilation_rul</i> Upper Lid	<i>meepilation_rll</i> Lower Lid	<i>meepilation_lul</i> Upper Lid	<i>meepilation_lll</i> Lower Lid
None	<input type="checkbox"/> _0	<input type="checkbox"/> _0	<input type="checkbox"/> _0	<input type="checkbox"/> _0
<1/3 of the lid margin	<input type="checkbox"/> _1	<input type="checkbox"/> _1	<input type="checkbox"/> _1	<input type="checkbox"/> _1
≥1/3 to ≤2/3 of the lid margin	<input type="checkbox"/> _2	<input type="checkbox"/> _2	<input type="checkbox"/> _2	<input type="checkbox"/> _2
>2/3 of the lid margin	<input type="checkbox"/> _3	<input type="checkbox"/> _3	<input type="checkbox"/> _3	<input type="checkbox"/> _3

8. Entropion:	Right Eye		Left Eye	
	<i>meentropion_rul</i> Upper Lid	<i>meentropion_rll</i> Lower Lid	<i>meentropion_lul</i> Upper Lid	<i>meentropion_lll</i> Lower Lid
E0: None	<input type="checkbox"/> _0	<input type="checkbox"/> _0	<input type="checkbox"/> _0	<input type="checkbox"/> _0
E1: Mild: (without cornea-lash base touch, ≤50% of lid margin)	<input type="checkbox"/> _1	<input type="checkbox"/> _1	<input type="checkbox"/> _1	<input type="checkbox"/> _1
E2: Moderate: (without cornea-lash base touch, >50% of lid margin)	<input type="checkbox"/> _2	<input type="checkbox"/> _2	<input type="checkbox"/> _2	<input type="checkbox"/> _2
E3: Severe: (with cornea-lash base touch, <50% of lid margin)	<input type="checkbox"/> _3	<input type="checkbox"/> _3	<input type="checkbox"/> _3	<input type="checkbox"/> _3
E4: Total: (with cornea-lash base touch, >50% of lid margin)	<input type="checkbox"/> _4	<input type="checkbox"/> _4	<input type="checkbox"/> _4	<input type="checkbox"/> _4

**FLuorometholone as Adjunctive MEDical Therapy for TT Surgery
(FLAME) Trial**

ME (009.2)
10/12/2021
Page 4 of 15



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

9A. Is there any Eyelid Contour Abnormality in the Right Eye ? mecontour_r	Yes <input type="checkbox"/> _1 No <input type="checkbox"/> _0
9Aa. Notch present in the Right Eye: menotchpre_r	Yes <input type="checkbox"/> _1 No <input type="checkbox"/> _0
Location (check all that apply):	Lateral <input type="checkbox"/> _1 menotchloc_r__1 Central <input type="checkbox"/> _1 menotchloc_r__2 Medial <input type="checkbox"/> _1 menotchloc_r__3 Not Applicable <input type="checkbox"/> _1 menotchloc_r__4
Severity: menotchsev_r	Mild <input type="checkbox"/> _1 Moderate <input type="checkbox"/> _2 Severe <input type="checkbox"/> _3 Not Applicable <input type="checkbox"/> _4
9Ab. Other kind of contour abnormality in the Right Eye meotherpre_r	Yes <input type="checkbox"/> _1 No <input type="checkbox"/> _0
Location (check all that apply):	Lateral <input type="checkbox"/> _1 meotherloc_r__1 Central <input type="checkbox"/> _1 meotherloc_r__2 Medial <input type="checkbox"/> _1 meotherloc_r__3 Not Applicable <input type="checkbox"/> _1 meotherloc_r__4
Severity: meothersev_r	Mild <input type="checkbox"/> _1 Moderate <input type="checkbox"/> _2 Severe <input type="checkbox"/> _3 Not Applicable <input type="checkbox"/> _4

**FLuorometholone as Adjunctive MEDical Therapy for TT Surgery
(FLAME) Trial**

ME (009.2)
10/12/2021
Page 5 of 15



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

9B. Is there any Eyelid Contour Abnormality in the Left Eye ? mecontour_I	Yes <input type="checkbox"/> _1 No <input type="checkbox"/> _0
9Ba. Notch present in the Left Eye: menotchpre_I	Yes <input type="checkbox"/> _1 No <input type="checkbox"/> _0
Location (check all that apply):	Lateral <input type="checkbox"/> _1 menotchloc_I__1 Central <input type="checkbox"/> _1 menotchloc_I__2 Medial <input type="checkbox"/> _1 menotchloc_I__3 Not Applicable <input type="checkbox"/> _1 menotchloc_I__4
Severity: menotchsev_I	Mild <input type="checkbox"/> _1 Moderate <input type="checkbox"/> _2 Severe <input type="checkbox"/> _3 Not Applicable <input type="checkbox"/> _4
9Bb. Other kind of contour abnormality in the Left Eye meotherpre_I	Yes <input type="checkbox"/> _1 No <input type="checkbox"/> _0
Location (check all that apply):	Lateral <input type="checkbox"/> _1 meotherloc_I__1 Central <input type="checkbox"/> _1 meotherloc_I__2 Medial <input type="checkbox"/> _1 meotherloc_I__3 Not Applicable <input type="checkbox"/> _1 meotherloc_I__4
Severity: meothersev_I	Mild <input type="checkbox"/> _1 Moderate <input type="checkbox"/> _2 Severe <input type="checkbox"/> _3 Not Applicable <input type="checkbox"/> _4



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

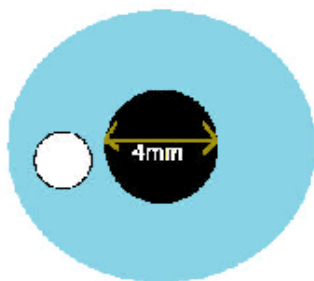
10. Corneal Opacity/Scar Grading (if more than one corneal scar, grade for worst /most central scar based on diagram below):	Right Eye	Left Eye
	<i>mecornealscar_r</i>	<i>mecornealscar_l</i>
C0: No Opacity	<input type="checkbox"/> 0	<input type="checkbox"/> 0
C1: Opacity not entering central 4mm	<input type="checkbox"/> 1	<input type="checkbox"/> 1
C2a: Opacity within central 4mm but not entering within the central 1mm of the cornea. The pupil margin is visible through the opacity.	<input type="checkbox"/> 2	<input type="checkbox"/> 2
C2b: Opacity within central 4mm but not entering within the central 1mm of the cornea. The pupil margin is not visible through the opacity.	<input type="checkbox"/> 3	<input type="checkbox"/> 3
C2c: Opacity within central 4mm and entering the central 1mm of the cornea. The pupil margin is visible through the opacity.	<input type="checkbox"/> 4	<input type="checkbox"/> 4
C2d: Opacity within central 4mm and entering within the central 1mm of the cornea. The pupil margin is not visible through the opacity.	<input type="checkbox"/> 5	<input type="checkbox"/> 5
C3: Opacity large enough and dense enough to make whole pupil margin invisible.	<input type="checkbox"/> 6	<input type="checkbox"/> 6
C4: Phthisis bulbi	<input type="checkbox"/> 7	<input type="checkbox"/> 7
10a. If Corneal Opacity is present, does it interfere with vision?		
Right Eye: Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 0 N/A <input type="checkbox"/> 2 <i>mecornealopa_r</i>	Left Eye: Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 0 N/A <input type="checkbox"/> 2 <i>mecornealopa_l</i>	



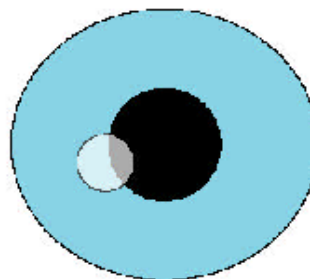
MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

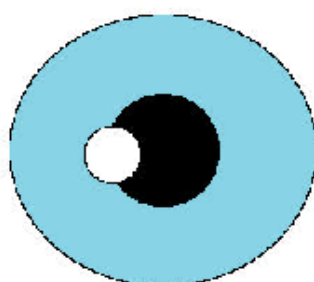
Corneal Scar Grading



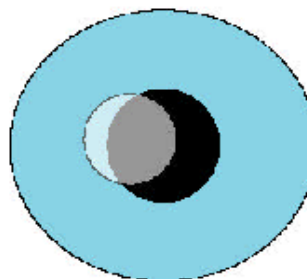
C1



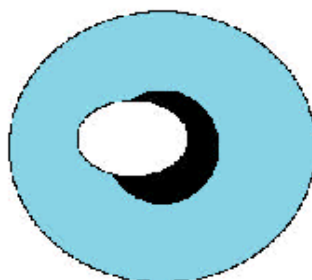
C2a



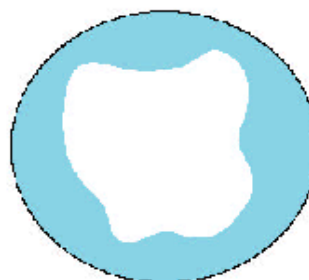
C2b



C2c



C2d



C3

**FLuorometholone as Adjunctive MEdical Therapy for TT Surgery
(FLAME) Trial**

ME (009.2)
10/12/2021
Page 8 of 15



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

11. Conjunctivalization of the Lid Margin Grade: Right Eye		
	meconjunct_rul Upper Lid	Lower Lid meconjunct_rll
CM0: None	<input type="checkbox"/> _0	<input type="checkbox"/> _0
CM1: Muco-cutaneous junction is located anterior to its normal position, but the whole line is still posterior to the line of the Meibomian gland orifices.	<input type="checkbox"/> _1	<input type="checkbox"/> _1
CM2: Muco-cutaneous junction is located anterior to the line of the Meibomian gland orifices for less than 50% of the lid.	<input type="checkbox"/> _2	<input type="checkbox"/> _2
CM3: Muco-cutaneous junction is located anterior to the line of the Meibomian gland orifices for greater than 50% of the lid.	<input type="checkbox"/> _3	<input type="checkbox"/> _3

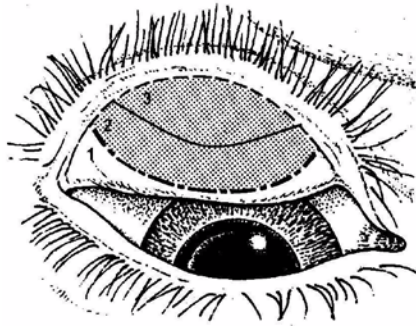
12. Trachoma Grading (check all that apply): Right Eye		
	Yes	No
TF: Trachomatous inflammation, follicular	<input type="checkbox"/> _1	<input type="checkbox"/> _0 metrachfoll_r
TI: Trachomatous inflammation, intense	<input type="checkbox"/> _1	<input type="checkbox"/> _0 metrachint_r
TS: Trachomatous scarring	<input type="checkbox"/> _1	<input type="checkbox"/> _0 metrachscar_r
TT: Trachomatous trichiasis	<input type="checkbox"/> _1	<input type="checkbox"/> _0 metrachtri_r
CO: Corneal Opacity	<input type="checkbox"/> _1	<input type="checkbox"/> _0 mecorneal_r



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

13. Upper Eyelid Follicles: (Refer to diagram below)	Right Eye mefoll_rul
F0: Absent	<input type="checkbox"/> 0
F1: Follicles present, but no more than 5 in zones 2 and 3 together.	<input type="checkbox"/> 1
F2: More than 5 follicles in zones 2 and 3 together, but less than 5 in zone 3.	<input type="checkbox"/> 2
F3: Five or more follicles in each of the three zones.	<input type="checkbox"/> 3



14. Upper Eyelid Papillary Hypertrophy:	Right Eye mepapilla_rul
P0: Absent, normal appearance.	<input type="checkbox"/> 0
P1: Minimal: individual vascular tufts (papillae) prominent, but deep subconjunctival vessels on the tarsus are not obscured.	<input type="checkbox"/> 1
P2: Moderate: more prominent papillae and normal vessels appear hazy, even as seen by the naked eye.	<input type="checkbox"/> 2
P3: Pronounced: conjunctiva thickened and opaque, normal vessels on the tarsus are hidden over more than half the surface.	<input type="checkbox"/> 3



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

15. Upper eyelid conjunctival scarring If prior lid surgery at the time of grading:

Right Eye *meconj_surg_rul*

SC0: No scarring on the conjunctiva. ☐ ₀

SC1: Surgical line only ☐ ₁

SC2: Surgical line and occasional scattered scars ☐ ₂

SC3: Surgical scar with widespread trachomatous
Scarring but no distortion ☐ ₃

SC4: Surgical scar with distortion immediately around the
Incision line ☐ ₄

SC5: Surgical scar with additional distortion secondary to
widespread trachomatous scarring ☐ ₅

SC6: Not applicable (no prior lid surgery) ☐ ₆

16. Conjunctivalization of the Lid Margin Grade: Left Eye

meconjunct_lul Upper Lid Lower Lid *meconjunct_lll*

CM0: None ☐ ₀ ☐ ₀

CM1: Muco-cutaneous junction is located anterior
to its normal position, but the whole line
is still posterior to the line of the Meibomian
gland orifices. ☐ ₁ ☐ ₁

CM2: Muco-cutaneous junction is located anterior
to the line of the Meibomian gland
orifices for less than 50% of the lid. ☐ ₂ ☐ ₂

CM3: Muco-cutaneous junction is located anterior
to the line of the Meibomian gland
orifices for greater than 50% of the lid. ☐ ₃ ☐ ₃

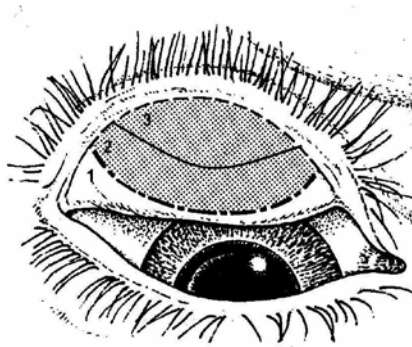


MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

17. Trachoma Grading (check all that apply): Left Eye		
	Yes	No
TF: Trachomatous inflammation, follicular metrachfoll_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
TI: Trachomatous inflammation, intense metrachint_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
TS: Trachomatous scarring metrachscar_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
TT: Trachomatous trichiasis metrachtri_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
CO: Corneal Opacity mecorneal_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0

18. Upper Eyelid Follicles: (Refer to diagram below) Left Eye mefoll_lul	
F0: Absent	<input type="checkbox"/> 0
F1: Follicles present, but no more than 5 in zones 2 and 3 together.	<input type="checkbox"/> 1
F2: More than 5 follicles in zones 2 and 3 together, but less than 5 in zone 3.	<input type="checkbox"/> 2
F3: Five or more follicles in each of the three zones.	<input type="checkbox"/> 3





MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

19. Upper Eyelid Papillary Hypertrophy: mepapilla_lul Left Eye

P0: Absent, normal appearance. ☐ 0

P1: Minimal: individual vascular tufts (papillae) prominent, but deep subconjunctival vessels on the tarsus are not obscured. ☐ 1

P2: Moderate: more prominent papillae and normal vessels appear hazy, even as seen by the naked eye. ☐ 2

P3: Pronounced: conjunctiva thickened and opaque, normal vessels on the tarsus are hidden over more than half the surface. ☐ 3

20. Upper eyelid conjunctival scarring If prior lid surgery at the time of grading: meconj_surg_lul Left Eye

SC0: No scarring on the conjunctiva. ☐ 0

SC1: Surgical line only ☐ 1

SC2: Surgical line and occasional scattered scars ☐ 2

SC3: Surgical scar with widespread trachomatous Scarring but no distortion ☐ 3

SC4: Surgical scar with distortion immediately around the Incision line ☐ 4

SC5: Surgical scar with additional distortion secondary to widespread trachomatous scarring ☐ 5

SC6: Not applicable (no prior lid surgery) ☐ 6



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

21A. Are any of the following present in the Right Eye? (Check all that apply) If any conditions are new since the last study visit, add to the Adverse Event Log.

		Yes	No
a. Cataract	mecataract_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
b. Aphakia	meaphakia_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
c. Pseudophakia	mepseudophakia_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
d. Symblepharon	mesymble_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
e. Blepharitis	mebleph_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
f. Lid Closure Defect	melidclos_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
g. Overcorrection	meovercorrection_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
h. Granuloma	megranuloma_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
i. Corneal Infection	mecornealinf_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
j. Conjunctival Infection	meconjinf_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
k. Other Infection	meotherinf_r	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Specify other infection: meotherinfsp_r _____			

**FLuorometholone as Adjunctive MEDical Therapy for TT Surgery
(FLAME) Trial**

ME (009.2)
10/12/2021
Page 14 of 15



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

21B. Are any of the following present in the Left Eye? (Check all that apply) If any conditions are new since the last study visit, add to the Adverse Event Log.

	Yes	No
a. Cataract mecataract_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
b. Aphakia meaphakia_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
c. Pseudophakia mepseudophakia_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
d. Symblepharon mesymble_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
e. Blepharitis mebleph_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
f. Lid Closure Defect melidclos_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
g. Overcorrection meovercorrection_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
h. Granuloma megranuloma_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
i. Corneal Infection mecornealinf_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
j. Conjunctival Infection meconjinf_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
k. Other Infection meotherinf_I	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Specify other infection: meotherinfsp_I		

**FLuorometholone as Adjunctive MEdical Therapy for TT Surgery
(FLAME) Trial**

ME (009.2)
10/12/2021
Page 15 of 15



MONTH 6 & 12 EYE EXAMINATION FORM

ID. No.: ____ - ____ Alpha Code: ____ Visit # ____

22. If vision in either eye is worse than logMAR 0.48, please indicate the most likely cause:

Right Eye mevision_r	Left Eye mevision_l
Not applicable <input type="checkbox"/> _1	Not applicable <input type="checkbox"/> _1
Refractive error <input type="checkbox"/> _2	Refractive error <input type="checkbox"/> _2
Cataract, untreated <input type="checkbox"/> _3	Cataract, untreated <input type="checkbox"/> _3
Aphakia, uncorrected <input type="checkbox"/> _4	Aphakia, uncorrected <input type="checkbox"/> _4
Pseudophakic, with uncorrected refractive error <input type="checkbox"/> _5	Pseudophakic, with uncorrected refractive error <input type="checkbox"/> _5
Surgical complications <input type="checkbox"/> _6	Surgical complications <input type="checkbox"/> _6
Trachoma <input type="checkbox"/> _7	Trachoma <input type="checkbox"/> _7
Phthisis <input type="checkbox"/> _8	Phthisis <input type="checkbox"/> _8
Other Corneal scar <input type="checkbox"/> _9	Other Corneal scar <input type="checkbox"/> _9
Other not listed: <input type="checkbox"/> _77	Other not listed: <input type="checkbox"/> _77
Specify other: mevisionsp_r	Specify other: mevisionsp_l
Unknown <input type="checkbox"/> _99	Unknown <input type="checkbox"/> _99

23. Were all exams/questions completed for both eyes? ☐_1 Yes ☐_0 No meexams
(If No, Explain Reason) meexamsoter

24. Were ocular photographs taken? mephotos

☐_1 Yes ☐_0 No

25. Name & certification number of
person performing examination:

- a. Print Name: _____
b. Certification #: _____

Data entry complete date: ____/____/____

Data entered by initial: ____