FLuorometholone as **A**djunctive **ME**dical Therapy for TT Surgery (**FLAME**) Trial

Protocol Deviation and Unanticipated Event Form

Complete this form to document a SINGLE Protocol Deviation or unanticipated event. form_id

1. Are you reporting a Protocol Deviation or Unanticipated Event (check only one box)? reportedevent

    a. Protocol Deviation ☐$_1$

    b. Unanticipated Event ☐$_1$

2. Type of Deviation or Unanticipated Event: (Check one only, one form per protocol deviation) eventtype

    a. Consent issue ☐$_1$

    b. Patient did not have upper lid TT surgery ☐$_1$

    c. Ineligible patient randomized ☐$_1$

    d. Patient did not use assigned eye drops ☐$_1$

    e. Study procedures not performed or performed incorrectly ☐$_1$

    f. Incorrect study treatment kit dispensed ☐$_1$

    g. Uncertified staff performed study procedures ☐$_1$

    h. Enrolled patient without tarsal conjunctival scarring before protocol change ☐$_1$

    i. Other ☐$_1$ Specify: typeothsp _____

3. Patient ID (if applicable): __ __ - subjid __ __ __ __   Not applicable ☐ patientidna

4. Deviation or Unanticipated Event Summary:	
a. Date or period of time when the deviation or unanticipated event occurred:	
b. Date when the deviation or unanticipated event was identified:	
c. Description of protocol deviation or unanticipated event:	

5. Reason the deviation or unanticipated event occurred:

6. Action Taken:

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7. Please provide a corrective action plan to prevent this from occurring in the future:

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8. Was the study masking broken?

$\square_0$ No $\square_1$ Yes maskbroken

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9. Deviation or Unanticipated Event Assessment: If any of these questions are answered Yes, the deviation or unanticipated event must be reported to the IRB.

a. Did this deviation or unanticipated event violate the rights or welfare of the subject? Why or Why not?

b. Did this deviation or unanticipated event have the potential to affect the subject's safety? Why or Why not?

c. Did this deviation or unanticipated event affect the integrity of the data? Why or Why not?

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10. Did the event meet IRB expedited reporting requirements (see #9 above)? irbreq

$\square_0$ No

$\square_1$ Yes ——————————————→

| Report protocol deviation or unanticipated event to IRB! |
| Date reported: __ __ /__ __ /20 __ __ |
| Reported by: _____ |

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11. Person completing this form (please print):

_____

12. Date form completed: __ __/ __ __ / 20 __ __
                                Day   Month   Year