Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Peribulbar Triamcinolone Acetonide Study

Enrollment Form

Obtain a Study ID

Patient Initials: ___ ___ ___ *(enter 'X' if no middle initial)*

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Date informed consent form signed for screening: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____ **DRCR ID#:** __ __ __ **-** __ __ __

Date of Birth: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy (age must be >= 18.0* yrs)

Which eye(s) is/are being evaluated for the study? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)
If you are not sure which eyes to evaluate to be a study eye, please select both eyes.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Date history elicited: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

A. DEMOGRAPHIC INFORMATION

1. **Date of Birth:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy (age must be >= 18.0* yrs)

2. **Gender:** Male Female

3. **Ethnicity:** Hispanic or Latino Not Hispanic or Latino Unknown/not reported

4. **Race:** White
   Black/African-American
   Asian
   Native Hawaiian/Other Pacific Islander
   American Indian/Alaskan Native
   More than one race
   Unknown/not reported

If more than one race selected please specify: _____

B. DIABETES HISTORY

1. **Age at diagnosis of diabetes:** _____ yrs old *enter approx age if patient is not precise and records are not available*

2. **Type of Diabetes:** Type 1 Type 2 Uncertain

3. **Diabetes treatment**
   None
   Diet only
   Insulin
   Oral
   Insulin + Oral

4. **If using insulin:**

   a. ☐ **pump** <u>**or**</u> ☐ **injections**_____ **/day** *daily average, leave blank for pump users.*

   b. **age when insulin treatment started** ____ yrs old *enter approx age if patient is not precise and records are not available*

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

C. MEDICAL HISTORY

(All boxes must be checked for eligibility)

Patient History
☐ **1. No history of renal failure requiring dialysis or kidney transplant.**
☐ **2. No known allergies to any corticosteroid or any component of the delivery vehicle.**
☐ **3. No condition (medical, social) that would preclude participation in the study (e.g., unstable medical status including blood pressure and glycemic control).**
☐ **4. Patient is NOT currently using topical, rectal, or inhaled corticosteroids more than 2 times per week.**
☐ **5. No steroid-induced intraocular pressure elevation that required IOP-lowering treatment in either eye.**
☐ **6. Patient is NOT expecting to move out of the area of the clinical center to an area not covered by another clinical center during the next 8 months.**
☐ **7. Patient is NOT currently taking Coumadin (Warfarin).**
☐ **8. Patient has NOT initiated intensive insulin treatment (a pump or multiple daily injections) within the past 4 months and does not plan to do so in the next 4 months.**
☐ **9. Patient has NOT been treated with systemic (e.g., oral, IV, IM, epidural, bursal) corticosteroids within past 4 months.**
☐ **10. Patient has NOT participated in an investigational trial within 30 days prior to study entry that involved treatment with any drug that has not received regulatory approval at time of study entry**.

Right Eye (OD) History **Complete this section if the Right Eye (OD) is being evaluated as a study eye.**
☐ **1. No prior intravitreal, peribulbar, or retrobulbar corticosteroids for DME in the right eye.**
☐ **2. No YAG laser capsulotomy within past 2 months in the right eye.**
☐ **3. No previous herpetic ocular infection in the right eye.**
☐ **4. No open-angle glaucoma in the right eye (either primary open-angle glaucoma or other cause of open-angle glaucoma; note: angle-closure glaucoma is not an exclusion).**
☐ **5. Patient has not received maximal laser treatment in the right eye.**
6 Does patient have a history of ocular hypertension in his/her right eye? Yes No **If YES, what treatment is currently prescribed? None/1 topical med/>1 topical med** *(If treatment is prescribed complete the Concomitant Medication Form)*

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Left Eye (OS) History

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

- ☐ **1. No prior intravitreal, peribulbar, or retrobulbar corticosteroids for DME in the left eye.**
- ☐ **2. No YAG laser capsulotomy within past 2 months in the left eye.**
- ☐ **3. No previous herpetic ocular infection in the left eye.**
- ☐ **4. No open-angle glaucoma in the left eye (either primary open-angle glaucoma or other cause of open-angle glaucoma; note: angle-closure glaucoma is not an exclusion).**
- ☐ **5. Patient has not received maximal laser treatment in the left eye.**

6 Does patient have a history of ocular hypertension in his/her left eye? Yes No

If YES, what treatment is currently prescribed? None/1 topical med/>1 topical med
(If treatment is prescribed complete the Concomitant Medication Form)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

D. STUDY EYE OCULAR PROCEDURE HISTORY

Complete this section if the Right Eye (OD) is being evaluated as a study eye.

1. Previous focal/grid laser photocoagulation in the macula *Must be NO or ≥ 15 weeks (3.5 months) ago for study eye eligibility*	No Yes, < 15 weeks (3.5 months) ago Yes, ≥ 15 weeks (3.5 months) ago
1a. If Yes, how many prior focal laser treatment session have been performed on the right eye? (If exact number is not know, enter best estimate)	1 2 ≥ 3
2. Previous panretinal scatter photocoagulation *Must be NO or all Rx ≥ 4 mos ago for study eye eligibility*	No Yes, < 4 mos ago Yes, all Rx ≥ 4 mos ago
3. Cataract Extraction *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
4. Vitrectomy *Must be No for study eye eligibility*	No Yes
5. Glaucoma filter/laser trabeculoplasty *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
6. Scleral buckle *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
7. Cornea transplant *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
8. Other ocular surgery *(Leave blank if no other surgeries)* *Must be ≥ 6 months ago for study eye eligibility* _____	< 6 mos ago ≥ 6 mos ago
9. Other ocular surgery *(Leave blank if no other surgeries)* *Must be ≥ 6 months ago for study eye eligibility* _____	< 6 mos ago ≥ 6 mos ago
10. Other ocular surgery *(Leave blank if no other surgeries)* *Must be ≥ 6 months ago for study eye eligibility* _____	< 6 mos ago ≥ 6 mos ago

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

1. Previous focal/grid laser photocoagulation in the macula *Must be NO or ≥ 15 weeks (3.5 months) ago for study eye eligibility*	No Yes, < 15 weeks (3.5 months) ago Yes, ≥ 15 weeks (3.5 months) ago
1a. If Yes, how many prior focal laser treatment session have been performed on the left eye? **(If exact number is not know, enter best estimate)**	1 2 ≥ 3
2. Previous panretinal scatter photocoagulation *Must be NO or all Rx ≥ 4 mos ago for study eye eligibility*	No Yes, < 4 mos ago Yes, all Rx ≥ 4 mos ago
3. Cataract Extraction *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
4. Vitrectomy *Must be No for study eye eligibility*	No Yes
5. Glaucoma filter/laser trabeculoplasty *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
6. Scleral buckle *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
7. Cornea transplant *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
8. Other ocular surgery *(Leave blank if no other surgeries)* *Must be ≥ 6 months ago for study eye eligibility* _____	< 6 mos ago ≥ 6 mos ago
9. Other ocular surgery *(Leave blank if no other surgeries)* *Must be ≥ 6 months ago for study eye eligibility* _____	< 6 mos ago ≥ 6 mos ago
10. Other ocular surgery *(Leave blank if no other surgeries)* *Must be ≥ 6 months ago for study eye eligibility* _____	< 6 mos ago ≥ 6 mos ago

E. MEDICATIONS

1. Is the patient currently using any medications or has the patient taken medications in the last 30 days?

☐ Yes ☐ No

(If Yes, record all medications on the Concomitant Medication Form.)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Visual Acuity

Test visual acuity of each eye without cycloplegia or dilation using Electronic ETDRS protocol

ETDRS Charts cannot be used for visual acuity testing at patient enrollment.

Refraction and Visual Acuity Testing must be done on same day and within 8 days prior to randomization

F. Correction

1. Is patient currently wearing corrective lenses? ☐ **Yes** ☐ **No**

1a. If Yes, record the correction: OD _____ _____ @ _____ ° **OS** _____ _____ @ _____ °
sph cyl axis sph cyl axis

G. Visual Acuity/Refraction

1. Visual Acuity testing date (includes refraction): ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be within 8 days prior to randomization)

2. Refraction: OD _____ _____ @ _____ ° **OS** _____ _____ @ _____ °
sph cyl axis sph cyl axis

3. Name of Refractionist: _____ **DRCR ID#:** __ __ __ - __ __ __

4. EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:
☐ 5. Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat
☐ 6. Brightness of screen within range on light meter
☐ 7. Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

If any aspects of the EVA testing were not completed according to the protocol, please detail in COMMENTS.

8. E-ETDRS letter score: OD _____ OS _____
To qualify as a study eye, visual acuity score must be ≥ 69 letters (approximately 20/40 or better)
ETDRS Charts cannot be used for visual acuity testing at patient enrollment.

9. Name of VA Tester: _____ **DRCR ID#:** __ __ __ - __ __ __

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Slit Lamp/ IOP Exam

Slit Lamp exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 21 days prior to randomization)

H. Slit Lamp

Complete this section if the Right Eye (OD) is being evaluated as a study eye.

1. Lids/ Conjunctiva: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

2. Cornea: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐ 20/ 25- 20/40 ☐ 20/50 -20/100 ☐ > 20/100

3. Iris neovascularization: ☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

1. Lids/ Conjunctiva: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

2. Cornea: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐ 20/ 25- 20/40 ☐ 20/50 -20/100 ☐ > 20/100

3. Iris neovascularization: ☐ Absent

☐ Present, pupillary margin only

☐ Present, beyond the margin, but not in the angle

☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

I. IOP

IOP measurement is required on both eyes.

IOP measurement date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

(Must be done within 21 days prior to randomization)

IOP Tester: _____

RIGHT EYE (OD)

1. Intraocular Pressure: _____ **mm Hg**

(Must be <25 mm Hg for eligibility)

Using Goldmann Tonometer

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

LEFT EYE (OS)

1. Intraocular Pressure: _____ mm Hg

(Must be <25 mm Hg for eligibility)

Using Goldmann Tonometer

Lens/ Dilated Fundus Exam

J. Lens Assessment

Lens exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

(Must be done within 21 days prior to randomization)

Lens assessment is required on both eyes.

Complete this section for the Right Eye (OD)

1. Lens Status *(Study eye must be Phakic or Pseudophakic for eligibility)*	☐ Phakic	☐ Pseudophakic	☐ Aphakic	
If Phakic, complete the following:				
2. Nuclear sclerosis	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
3. Posterior subcapsular cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
4. Cortical cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
5. If lens opacity(ies) present, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ > 20/100
If Pseudophakic or Aphakic, complete the following:				
6. Posterior capsular opacity?	☐ Yes	☐ No		
7. If Yes, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section for the Left Eye (OS)

1. Lens Status *(Study eye must be Phakic or Pseudophakic for eligibility)*	☐ Phakic	☐ Pseudophakic	☐ Aphakic	
If Phakic, complete the following:				
2. Nuclear sclerosis	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
3. Posterior subcapsular cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
4. Cortical cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
5. If lens opacity(ies) present, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ . > 20/100
If Pseudophakic or Aphakic, complete the following:				
6. Posterior capsular opacity?	☐ Yes	☐ No		
7. If Yes, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ . > 20/100

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

K. Dilated Fundus Exam

Dilated Fundus exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

(Must be done within 21 days prior to randomization)

Complete this section if the Right Eye (OD) is being evaluated as a study eye.

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy: ☐ No ☐ Yes

If Yes complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

4. Optic disc: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

(Must be present if right eye is being evaluated as a study eye)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

2. Vitreous (other than vitreous hemorrhage): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy: ☐ No ☐ Yes

If Yes complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

4. Optic disc: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine
(Must be present if left eye is being evaluated as a study eye)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

L. Miscellaneous Eligibility Checks

Ocular exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 21 days prior to randomization)

Complete this section if the Right Eye (OD) is being evaluated as a study eye.

(All boxes must be checked for eligibility)

☐ **1. Panretinal photocoagulation is NOT expected to be needed in the right eye in the next 4 months.**

☐ **2. Major ocular surgery (including cataract extraction, scleral buckle, any intraocular surgery, etc.) is NOT expected to be needed in the right eye within the next 6 months following randomization.**

☐ **3. The right eye does NOT have evidence of an ocular condition such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g. foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).**

☐ **4. The right eye does NOT have evidence of an ocular condition (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome).**

☐ **5. No evidence of ocular toxoplasmosis in the right eye.**

☐ **6. Pseudoexfoliation NOT present in the right eye.**

☐ **7. The edema in the macula is most likely due to diabetes and NOT another condition such as cataract extraction or vitreoretinal interface disease (e.g. a taut posterior hyaloid or epriretinal membrane).**

☐ **8. (1) Media clarity, (2) pupillary dilation, and (3) patient cooperation were sufficient for adequate fundus photos in the right eye.**

☐ **9. One of the following is true:**

(1) Right eye does not have a history of ocular hypertension AND IOP is < 22 mm Hg

OR

(2) Right eye has a history of ocular hypertension or IOP is 22 - < 25 AND all of the following are true: (i) IOP <25 mm Hg, (ii) most recent visual field performed within past 12 months is normal, (iii) patient is using 1 or no topical glaucoma medications, AND (iv) optic disc does NOT appear glaucomatous.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

(All boxes must be checked for eligibility)

☐ **1. Panretinal photocoagulation is NOT expected to be needed in the left eye in the next 4 months.**

☐ **2. Major ocular surgery (including cataract extraction, scleral buckle, any intraocular surgery, etc.) is NOT expected to be needed in the left eye within the next 6 months following randomization.**

☐ **3. The left eye does NOT have evidence of an ocular condition such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g. foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).**

☐ **4. The left eye does NOT have evidence of an ocular condition (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome).**

☐ **5. No evidence of ocular toxoplasmosis in the left eye.**

☐ **6. Pseudoexfoliation NOT present in the left eye.**

☐ **7. The edema in the macula is most likely due to diabetes and NOT another condition such as cataract extraction or vitreoretinal interface disease (e.g. a taut posterior hyaloid or epriretinal membrane).**

☐ **8. (1) Media clarity, (2) pupillary dilation, and (3) patient cooperation were sufficient for adequate fundus photos in the left eye.**

☐ **9. One of the following is true:**

(1) Left eye does not have a history of ocular hypertension AND IOP is < 22 mm Hg

OR

(2) Left eye has a history of ocular hypertension or IOP is 22 - < 25 AND all of the following are true: (i) IOP <25 mm Hg, (ii) most recent visual field performed within past 12 months is normal, (iii) patient is using 1 or no topical glaucoma medications, AND (iv) optic disc does NOT appear glaucomatous.

M. Blood Pressure

1. Blood Pressure exam date: ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 21 days prior to randomization)

2. Blood Pressure: _____/_____ mm *(Measure in sitting position after patient has been sitting for at least 5 minutes)*
Must be performed within 21 days of randomization
Must be ≤ 180/110 to be eligible

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

N. OCT

1. OCT: Date Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
Must be performed within 21 days of randomization

2. OCT: Time Performed: _____:_____ am/pm

3. OCT Technician ID: __ __ __ - __ __ __

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

5. Eyes with OCT: ☐Right (OD) ☐Left (OS) ☐ Both (OU)

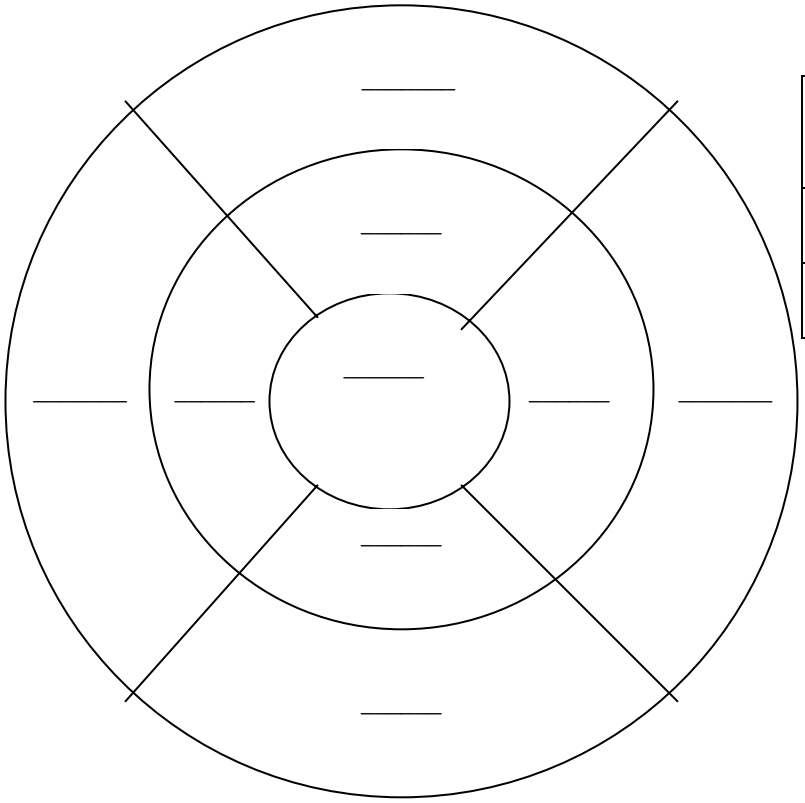
6. If not OU then Explain: _____
_____
_____

Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

COMPLETE THE FOLLOWING SECTION FOR THE RIGHT EYE

Enter the thickness for each of the subfields in the diagram shown below.
OCT central subfield measurements must be >= 250 microns for study eye eligibility

Right Eye (OD)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

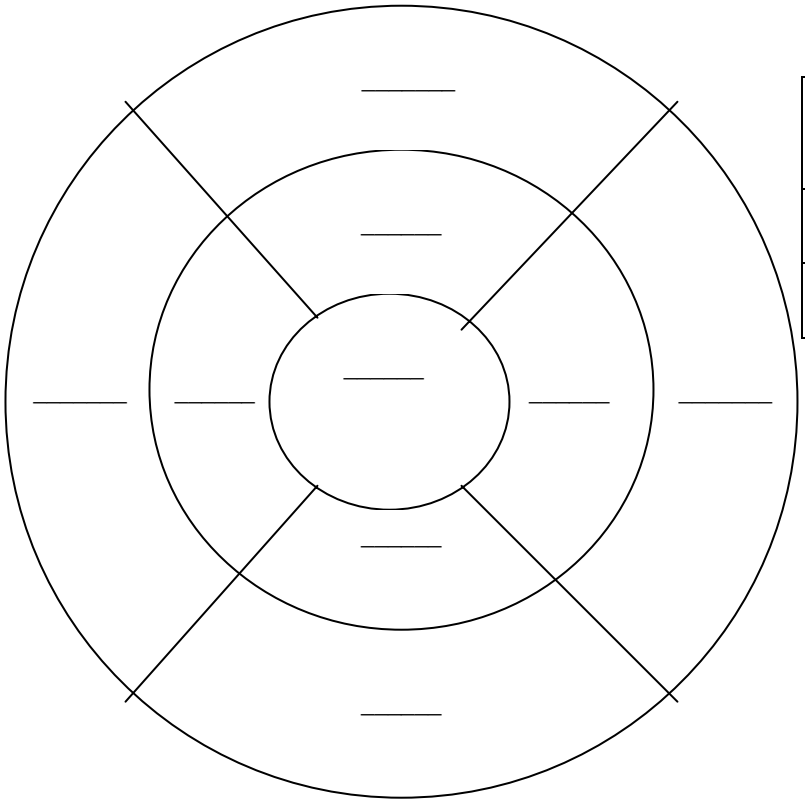
Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

COMPLETE THE FOLLOWING SECTION FOR THE LEFT EYE

Enter the thickness for each of the subfields in the diagram shown below.
OCT central subfield measurements must be >= 250 microns for study eye eligibility

Left Eye (OS)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

O. Fundus Photos

1a. ETDRS Fundus Photos: Date Performed (7-fields and Fundus (Red) Reflex):
___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
Must be performed in both eyes within 21 days of randomization

1b. Photographer ID: __ __ __ **-** __ __ __

1c. Eyes with Photos: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

1d. If not OU then Explain: _____

1e. Camera Used: _____

2. Was a fluorescein angiogram performed? ☐ Yes ☐ No
(If Yes, please complete the fluorescein angiogram form)

P. FLUORESCEIN ANGIOGRAPHY

(Only perform fluorescein angiography if part of usual care)

1a. Fluorescein Angiography: Date Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

1b. Fluorescein Angiographer ID: _____

1c. Eyes with Fluorescein Angiography: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

1d. Rapid Series Eye: ☐ Right (OD) ☐ Left (OS)

1e. Fluorescein Angiography Type: Film Digital

1f. Fluorescein Angiography done according to protocol? Yes No

Q. HbA1c

	Collection Date	Value	Lab Normal Range (Low Value to High Value)	Not completed but will be completed within 3 weeks.	Missed? *
HbA1c	___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____	☐	☐

***If missed provide reason in comments section**

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Baseline Visit Form

R. Randomization

1. Date informed consent form sign ed for trial: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
2. Have all signatures and date fields been properly completed on the informed consent form? Yes No *must be YES for patient eligibility* *Fax Signature Page to the Jaeb Center* at **1-800-816-7601**
3. Has the Patient Contact Information Form been completed? Yes No *Must be YES before patient can be randomized* *Fax Form to the Jaeb Center* at **1-800-816-7601**
4. Were any of the data (other than visual acuity, refraction, and labs) recorded on this form transcribed <u>DIRECTLY</u> from another source (i.e., medical record, surgical notes, patient study worksheet) rather than being confirmed with the patient and directly entered on the website? Yes No *If yes, please fax the source documents to the Jaeb Center for review at 1-800-816-7601.*
5. Has a study investigator verified the patient's eligibility? Yes No *Must be YES for patient eligibility*
6. Is patient ready to have treatment (laser or peribulbar injection) today or within 7 days? Yes No *Must be YES for patient eligibility*
7. Name of Investigator _____ **DRCR ID#:** _____

S. COMMENTS

T. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

Peribulbar Triamcinolone Acetonide Study

Pre-Existing Condition Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Date History Elicited: Enter date: ___ ___ / ____ ____ ____ / ___ ___ dd/mmm/yy

1. Does the patient have any past or present medical conditions other than Diabetes Mellitus? YES NO

If Yes, check the appropriate disorders/systems, indicate if active and being treated and for the systems, describe the condition.

	Active?	**Currently Being Treated?**
☐ Hypertension	Yes No	Yes No
☐ Elevated Cholesterol	Yes No	Yes No
☐ Elevated Triglycerides	Yes No	Yes No

System **Note: Enter only one condition per system. If patient has more than one pre-existing condition for a given system, please enter the additional conditions at the bottom of the form where indicated**	**Description of Pre-Existing Condition**	**Active?**	**Currently Being Treated?**
☐ ENT		Yes No	Yes No
☐ Cardiovascular		Yes No	Yes No
☐ Respiratory		Yes No	Yes No
☐ Gastrointestinal		Yes No	Yes No
☐ Renal (kidney)		Yes No	Yes No
☐ Genitourinary		Yes No	Yes No
☐ Hepatic (Liver)		Yes No	Yes No

(Continued on next page)

Peribulbar Triamcinolone Acetonide Study

Pre-Existing Condition Form

System **Note: Enter only one condition per system. If patient has more than one pre-existing condition for a given system, please enter the additional conditions at the bottom of the form where indicated**	**Description of Pre-Existing Condition**	**Active?**	**Currently Being Treated?**
☐ Endocrine (other than Diabetes Mellitus)		Yes No	Yes No
☐ Neurological		Yes No	Yes No
☐ Musculoskeletal		Yes No	Yes No
☐ Skin		Yes No	Yes No
☐ Psychological		Yes No	Yes No
☐ Blood/Lymphatic		Yes No	Yes No
☐ Allergy		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No

(Continued on next page)

Peribulbar Triamcinolone Acetonide Study

Pre-Existing Condition Form

System **Note: Enter only one condition per system. If patient has more than one pre-existing condition for a given system, please enter the additional conditions at the bottom of the form where indicated**	**Description of Pre-Existing Condition**	**Active?**	**Currently Being Treated?**
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No

Intravitreal Triamcinolone Acetonide Study

Concomitant Medications Form

(One form Per Medication)

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___

1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

1. Medication Name: _____ **brand name/ generic name**

2. Dose per administration (include unit): _____ ☐ **Unknown**

3. Route: S.C.-subcutaneous
I.V.-intravenous
Gtt-drops
I.D.-intradermal
I.M.-intramuscular
P.O.-by mouth
P.R.-by rectum
Topical
Vaginal

4. Frequency: _____ (1-50) per _____ (day, week, month, year) ☐ **Unknown**

4a. Same dose consistent (e.g. same dose every day)? Yes No

If 'No', explain: _____

5. Indication: Treatment of diabetes
Pre-existing condition
Treatment for an Adverse Event
Other

Intravitreal Triamcinolone Acetonide Study

Concomitant Medications Form

(One form Per Medication)

5a. If 'Pre-existing condition', select system:

ENT
Cardiovascular
Respiratory
Gastrointestinal
Renal (Kidney)
Genitourinary
Hepatic (Liver)
Endocrine
Ophthalmic System
Neurological
Musculosketal
Skin
Psychological
Blood/Lymphatic
Allergy
Other _____

5b. If 'Treatment for Adverse Event', enter Adverse Event: _____

6. Start Date: If < 30 days, enter date: ___ ___/___ ___ ___/ ___ ___ dd/mmm/yy

If >30 days, select date range:

> 30 days ago to 3 months ago
> 3 months ago to 6 month ago
> 6 months ago to 1 year ago
> 1 year ago to 5 years ago
> 5 years ago to 10 years ago
> 10 years ago

7. Stop Date (or mark box if ongoing): ___ ___/___ ___ ___/ ___ ___ dd/mmm/yy ☐ **Ongoing**

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Peribulbar Triamcinolone Acetonide Study

Anterior Peribulbar Injection Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Treatment Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____ **DRCR ID#:** _____

Procedure- (See DRCRnet study procedures manual for anterior injection procedure)

1. Eye Treated: OD OS

2. Injection Type: Posterior Anterior

Anesthetic Used

(Check all that apply)

☐ Topical anesthetic drop (record names(s) and concentration(s) below).

☐ Cotton-tipped applicator soaked in topical anesthetic over the injection site.

☐ Subconjunctival bleb of xylocaine.

☐ 1% Lidocaine gel over the injection site.

☐ Other (describe below)_____

Injection

Was the injection administered anterior to the junction of the bulbar and the palpebral conjunctiva as per the injection procedure? Yes No

If No, explain: _____

Post-Injection

Did the patient experience a subconjunctival hemorrhage post injection? Yes No
(If 'Yes' do NOT complete an Adverse Event Form)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Peribulbar Triamcinolone Acetonide Study

Anterior Peribulbar Injection Form

Adverse Events:

Did the patient experience any complications from the peribulbar injection (other than a subconjunctival hemorrhage)? Yes No

(If Yes, complete an Adverse Event Form)

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Peribulbar Triamcinolone Acetonide Study

Posterior Peribulbar Injection Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Treatment Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____ **DRCR ID#:** _____

Procedure- (See DRCRnet study procedures manual for posterior injection procedure)

1. Eye Treated: OD OS

2. Injection Type: Posterior Anterior

Anesthetic Used

(Check all that apply)

☐ Topical anesthetic drop (record names(s) and concentration(s) below).

☐ Cotton-tipped applicator soaked in topical anesthetic over the injection site.

☐ Subconjunctival bleb of xylocaine.

☐ 1% Lidocaine gel over the injection site.

☐ Other (describe below)_____

Injection

Was the injection administered 10 mm posterior to the limbus in the superotemperal quadrant of the eye as per the injection procedure? Yes No

If No, explain: _____

Post-Injection

Is ballooning of the anterior conjunctiva present? Yes No

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Peribulbar Triamcinolone Acetonide Study

Posterior Peribulbar Injection Form

Adverse Events:

Did the patient experience any complications from the posterior peribulbar injection? Yes No *(If Yes, complete an Adverse Event Form)*

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Peribulbar Triamcinolone Acetonide Study

Laser Photocoagulation Treatment Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Laser photocoagulation should be given using the modified-ETDRS treatment technique.

Treatment Date: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____ **DRCR ID#:** _____

A. Technique Performed

1. Eye Treated OD OS

2. Was 50 micron burn size used as per the protocol? Yes No

2a. If no, why not? _____

3. Average Power: _____ **mW**

4. Wave Length: Green Yellow

5. Number of Burns: _____

6. Was the treatment guided by Fluorescein Angiography? Yes No
Only Baseline & 4 Month fluorescein angiograms should be sent to the reading center

7. Did the patient experience any complications (e.g., heme, foveal burn, break in Bruch's membrane)? Yes No
If Yes, detail in the COMMENT section and complete an Adverse Event Form

8. Was the full treatment session completed in today's sitting? Yes No

B. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Peribulbar Triamcinolone Acetonide Study

Post-Laser Photography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

1a. ETDRS Fundus Photos: Date Performed (Field 2 Stereo Photos): ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

1b. Name of Photographer: _____ **DRCR ID#:** _____

1c. Eyes with Photos: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

1d. Camera Used: _____

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___

1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Visit Type: 4 Week 8 Week 4-Week post-injection safety

Name of Investigator _____ **DRCR ID#:** _____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. **Did patient commence or change the usage of any medications since last visit?** ☐ Yes ☐ No
   (If Yes, complete the Concomitant Medication Form.)
2. **Did the patient experience any of the following?** ☐ Yes ☐ No
   If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

B. Study Eye Ocular Treatment Update

RIGHT EYE (OD)

Complete the following if the right eye is a study eye.

1. Has the patient received any treatment for DME in the study right eye since the last visit (i.e. treatment was received at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No

If Yes, explain and provide dates:

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

LEFT EYE (OS)

Complete the following if the left eye is a study eye.

1. Has the patient received any treatment for DME in the study left eye since the last visit (i.e. treatment was received at a non-study site and therefore not recorded on a prior study case report form)? □ Yes □ No **If Yes, explain and provide dates:**

Visual Acuity

Visual acuity measurement is required in both eyes without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

Refraction is not required, but generally should be performed if there is an unexplained decrease of 15 letters or more since the last refraction.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Visual Acuity testing date (includes refraction if performed): ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

C. Refraction

1. Was a refraction performed at this visit prior to initial visual acuity testing? ☐ Yes ☐ No

1a. If Yes: Name of Refractionist: _____ **DRCR ID#:** _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

2. Refraction/ Correction Used: OD _____ _____ @ _____ o **OS** _____ _____ @ _____ o
sph cyl axis sph cyl axis

D. Visual Acuity

Visual acuity measurement is required in both eyes at this visit.

1. EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:
☐ 2. Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat
☐ 3. Brightness of screen within range on light meter
☐ 4. Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

5. ETDRS letter score: OD _____

OS _____

6. Name of VA Tester: _____ **DRCR ID#:** _____

7. Was the visual acuity tester masked to the patient's treatment group? Yes No

☐ **8. Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

Repeat Visual Acuity Section (optional)

Refraction and/or repeat visual acuity should be performed in the study eye(s) if there has been an unexplained 15-letter visual acuity loss since the previous refraction.

E. Repeat Refraction

1. Was a refraction performed after the initial visual acuity testing in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter refraction and refractionist below:

2. Name of Refractionist: _____ **DRCR ID#:** _____

3. Refraction: **OD** _____ _____ @ _____ ° **OS** _____ _____ @ _____ °
sph cyl axis sph cyl axis

F. Repeat Visual Acuity

1. Was visual acuity testing repeated in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter below:

2. EVA Instrument # *(from label):* _____

3. ETDRS letter score: OD _____

OS _____

4. Name of VA Tester: _____ **DRCR ID#:** _____

☐ **5. Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

G. Slit Lamp Exam

Slit lamp exam is required on the study eye(s) only.

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Slit lamp exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

RIGHT EYE (OD)

Complete this section if the Right Eye (OD) is a study eye.

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

LEFT EYE (OS)

Complete this section if the Left Eye (OS) is a study eye.

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

H. Intraocular Pressure Measurement

IOP measurement is required in both eyes.

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

IOP measurement date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

IOP Tester: _____

H1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*	**Right eye (OD)?**	Yes	No
	Left eye (OS)?	Yes	No

H2. IOP Measurement

RIGHT EYE (OD)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

LEFT EYE (OS)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP

Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is >= 30 mmHg at one visit or >25 mm Hg for 17 Week or more. The treatment to prescribe will be at investigator's discretion and may include referral to another ophthalmologist.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

I. Lens Assessment

(See procedure manual for lens assessment procedure)

A lens assessment exam is optional

Will a lens assessment be performed on the RIGHT eye at this visit? **Yes** **No**

If No, reason: _____

Will a lens assessment be performed on the LEFT eye at this visit? **Yes** **No**

If No, reason: _____

Lens assessment date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

RIGHT EYE (OD)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

LEFT EYE (OS)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
f Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

J. Fundus Exam

Dilated fundus exam is required on the study eye(s).

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Dilated fundus exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

Complete this section if the Right Eye (OD) is a study eye.

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

Complete this section if the Left Eye (OS) is a study eye.

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

K. OCT

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

OCT is required in both eyes.

Will OCT be performed on the RIGHT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

Will OCT be performed on the LEFT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

1. Date OCT Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

2. Time OCT Performed: ____ : _____ am/ pm

3. OCT Technician: _____

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

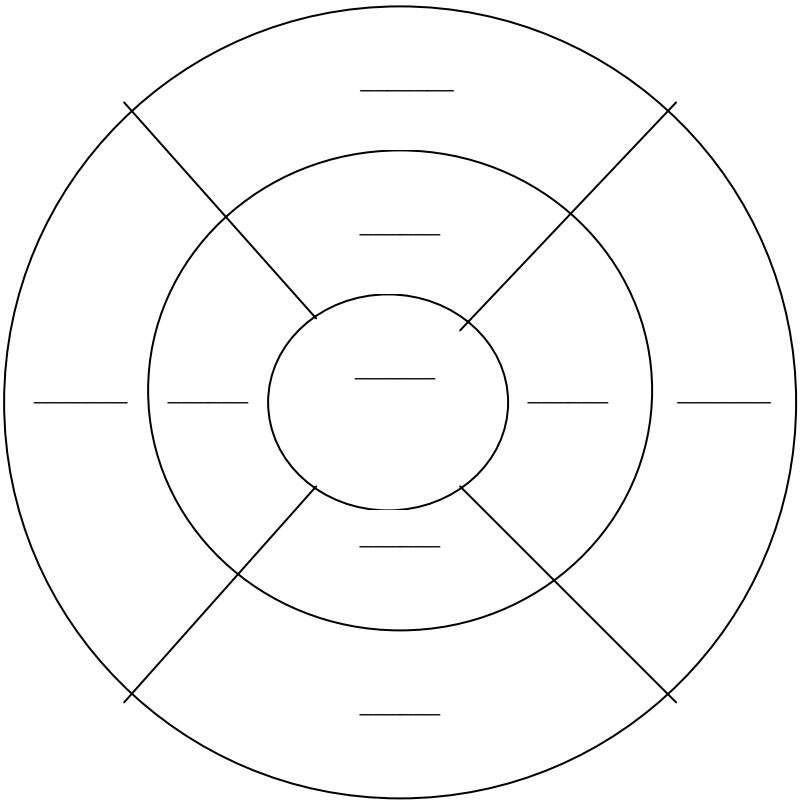
4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

RGHT EYE (OD)

OCT is required on the right eye

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(IF OCT 3 Version 4 was used please enter signal strength)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

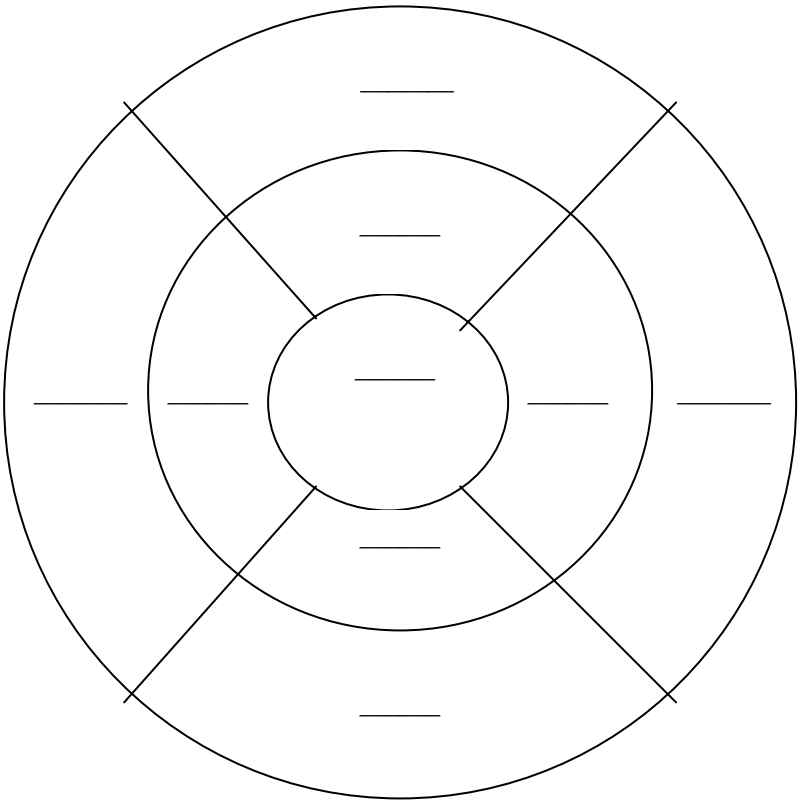
Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

LEFT EYE (OS)

OCT is required on the left eye

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(IF OCT 3 Version 4 was used please enter signal strength)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

L. COMMENTS

M. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

Complete Only After all Other Follow-Up Sections Are Completed

A. Treatment of Study Eye

Complete this section if the Right Eye (OD) is a study eye.

Skip to #2 if the right eye was NOT randomized to injection plus laser OR the right eye is NOT scheduled to receive laser photocoagulation treatment at this visit.

1. Will laser photocoagulation be performed on the right eye at this visit (only for eyes randomized to injection plus laser who are scheduled to receive laser at this visit)? Yes No

a. If 'No', reason:
Contraindicated
Patient Refuses
Other _____

2. Will the right eye receive a treatment other than the protocol defined treatment? Yes No
If visual acuity in the study eye has decreased by 15 or more letters from baseline (replicated after a repeat refraction), then any treatment may be given at investigator discretion.

Mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Anterior Peribulbar Triamcinolone Acetonide**
- ☐ **Posterior Peribulbar Triamcinolone Acetonide**
- ☐ **Intravitreal Triamcinolone Acetonide**
- ☐ **Other** _____

3. If the right eye is <u>not</u> being retreated with the randomized treatment, timing of next follow up visit for this eye: _____ [wks/mos]

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

4 Week, 8 Week, 4-Week Post-Injection Safety Visit Form

Complete this section if the Left Eye (OS) is a study eye.

Skip to #2 if the left eye was NOT randomized to injection plus laser OR the left eye is NOT scheduled to receive laser photocoagulation treatment at this visit.

1. Will laser photocoagulation be performed on the left eye at this visit (only for eyes randomized to injection plus laser who are scheduled to receive laser at this visit)? Yes No

a. If 'No', reason:
Contraindicated
Patient Refuses
Other _____

2. Will the left eye receive a treatment other than the protocol defined treatment? Yes No
If visual acuity in the study eye has decreased by 15 or more letters from baseline (replicated after a repeat refraction), then any treatment may be given at investigator discretion.

Mark all treatments that apply

☐ **Laser Photocoagulation**

☐ **Anterior Peribulbar Triamcinolone Acetonide**

☐ **Posterior Peribulbar Triamcinolone Acetonide**

☐ **Intravitreal Triamcinolone Acetonide**

☐ **Other** _____

3. If the left eye is <u>not</u> being retreated with the randomized treatment, timing of next follow up visit for this eye: _____ [wks/mos]

.

Were any of the data (other than visual acuity, refraction, and labs) recorded on this form transcribed <u>DIRECTLY</u> from another source (i.e., medical record, surgical notes, patient study worksheet) rather than being confirmed with the patient and directly entered on the website? Yes No

If yes, please fax the source documents to the Jaeb Center for review at 1-800-816-7601.

<u>COMMENTS</u>

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Visit Type: 17 Week 34 Week

Name of Investigator _____ **DRCR ID#:** _____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. **Did patient commence or change the usage of any medications since last visit?** ☐ Yes ☐ No
   (If Yes, complete the Concomitant Medication Form.)
2. **Did the patient experience any of the following?** ☐ Yes ☐ No
   If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

B. Study Eye Ocular Treatment Update

RIGHT EYE (OD)

Complete the following if the right eye is a study eye.

1. Has the patient received any treatment for DME in the study right eye since the last visit (i.e. treatment was received at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No

If Yes, explain and provide dates:

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

LEFT EYE (OS)

Complete the following if the left eye is a study eye.

1. Has the patient received any treatment for DME in the study left eye since the last visit (i.e. treatment was received at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No **If Yes, explain and provide dates:**

Visual Acuity

If 17 Week Visit:

Visual acuity measurement is required in both eyes without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

Refraction is not required, but generally should be performed if there is an unexplained decrease of 15 letters or more since the last refraction.

If 34 Week Visit:

Refraction is required at this visit. Visual acuity measurement is required in both eyes after refraction, without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Visual Acuity testing date (includes refraction if performed): ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

C. Refraction

1. Was a refraction performed at this visit prior to initial visual acuity testing? ☐ Yes ☐ No

1a. If Yes: Name of Refractionist: _____ **DRCR ID#:** _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

2. Refraction/ Correction Used: OD _____ _____ @ _____ o **OS** _____ _____ @ _____ o
sph cyl axis sph cyl axis

D. Visual Acuity

Visual acuity measurement is required in both eyes at this visit.

1. EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:
☐ 2. Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat
☐ 3. Brightness of screen within range on light meter
☐ 4. Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

5. ETDRS letter score: OD _____

OS _____

6. Name of VA Tester: _____ **DRCR ID#:** _____

7. Was the visual acuity tester masked to the patient's treatment group? Yes No

☐ **8. Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

Repeat Visual Acuity Section (optional)

Refraction and/or repeat visual acuity should be performed in the study eye(s) if there has been an unexplained 15-letter visual acuity loss since the previous refraction.

E. Repeat Refraction

1. Was a refraction performed after the initial visual acuity testing in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter refraction and refractionist below:

2. Name of Refractionist: _____ **DRCR ID#:** _____

3. Refraction: **OD** _____ _____ @ _____ ° **OS** _____ _____ @ _____ °
sph cyl axis sph cyl axis

F. Repeat Visual Acuity

1. Was visual acuity testing repeated in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter below:

2. EVA Instrument # *(from label):* _____

3. ETDRS letter score: OD _____

OS _____

4. Name of VA Tester: _____ **DRCR ID#:** _____

☐ **5. Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

G. Slit Lamp Exam

Slit lamp exam is required on the study eye(s) only.

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Slit lamp exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

RIGHT EYE (OD)

Complete this section if the Right Eye (OD) is a study eye.

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

LEFT EYE (OS)

Complete this section if the Left Eye (OS) is a study eye.

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

H. Intraocular Pressure Measurement

IOP measurement is required in both eyes.

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

IOP measurement date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

IOP Tester: _____

H1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*	**Right eye (OD)?**	Yes	No
	Left eye (OS)?	Yes	No

H2. IOP Measurement

RIGHT EYE (OD)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

LEFT EYE (OS)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP

Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is >= 30 mmHg at one visit or >25 mm Hg for 17 Week or more. The treatment to prescribe will be at investigator's discretion and may include referral to another ophthalmologist.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

I. Lens Assessment

(See procedure manual for lens assessment procedure)

Lens assessment is required in both eyes.

Will a lens assessment be performed on the RIGHT eye at this visit? **Yes** **No**

If No, reason: _____

Will a lens assessment be performed on the LEFT eye at this visit? **Yes** **No**

If No, reason: _____

Lens assessment date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

RIGHT EYE (OD)

1. Lens Status ☐ Phakic ☐ Pseudophakic ☐ Aphakic

If Phakic, complete the following:

2. Nuclear sclerosis *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

3. Posterior subcapsular cataract *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

4. Cortical cataract *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

5. If lens opacity(ies) present, estimated effect on visual acuity ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

If Pseudophakic or Aphakic, complete the following:

6. Posterior capsular opacity? ☐ Yes ☐ No

7. If Yes, estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

LEFT EYE (OS)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

J. Fundus Exam

Dilated fundus exam is required on the study eye(s).

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Dilated fundus exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

Complete this section if the Right Eye (OD) is a study eye.

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

Complete this section if the Left Eye (OS) is a study eye.

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

K. OCT

OCT is required in both eyes.

Will OCT be performed on the RIGHT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

Will OCT be performed on the LEFT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

1. Date OCT Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

2. Time OCT Performed: ____ : _____ am/ pm

3. OCT Technician: _____

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

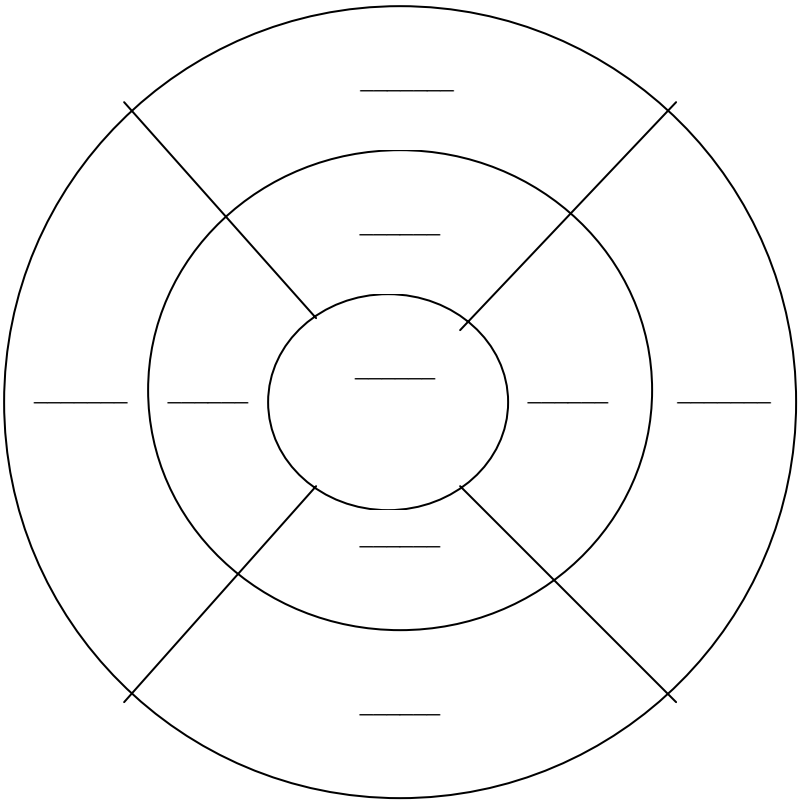
17 Week and 34 Week Visit Form

Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

RIGHT EYE (OD)

OCT is required on the right eye

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(IF OCT 3 Version 4 was used please enter signal strength)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

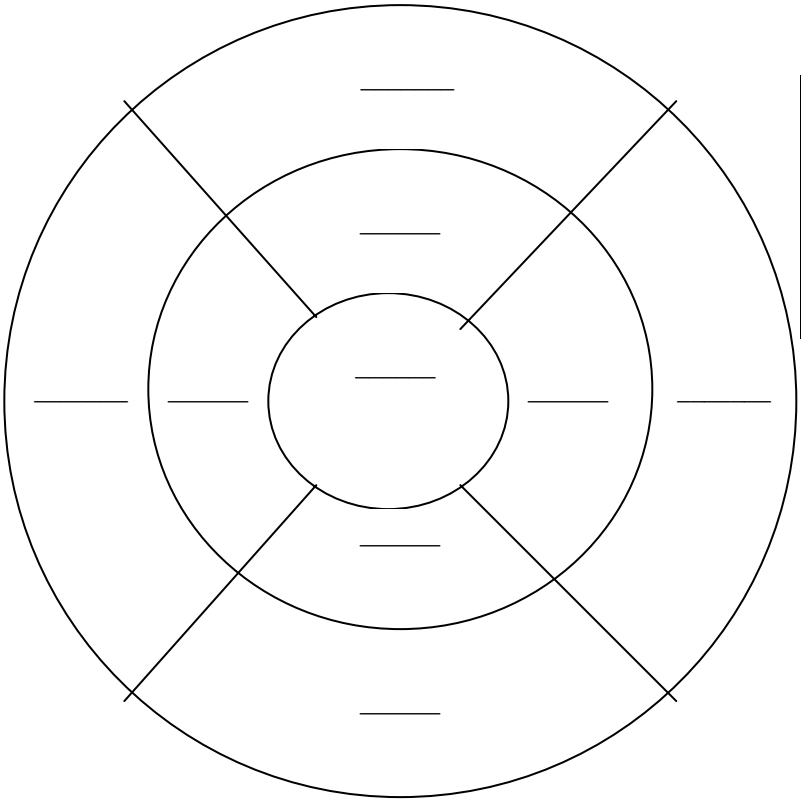
Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

LEFT EYE (OS)

OCT is required on the left eye

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(IF OCT 3 Version 4 was used please enter signal strength)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

L. Fundus Photography

If 17 Week visit, 3-Field and Fundus (Red) Reflex fundus photos are required to be performed in both eyes.

If 34 Week visit, 7-Field and Fundus (Red) Reflex fundus photos are required to be performed in both eyes.

Will fundus photos be taken on the RIGHT eye? Yes No

If No, reason: Media clarity insufficient
Pupillary dilation insufficient
Patient cooperation insufficient
Equipment failure
Film processing difficulties
Other_____

Will fundus photos be taken on the LEFT eye? Yes No

If No, reason: Media clarity insufficient
Pupillary dilation insufficient
Patient cooperation insufficient
Equipment failure
Film processing difficulties
Other_____

Date ETDRS Fundus Photos Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Note: If Media clarity or Pupillary dilation is insufficient for fundus photos, please obtain reflex photos. If only reflex photos are obtained, record this in the 'What photographs were completed?' portion of the form.

1. Name of Photographer: _____ **DRCR ID#:** _____

2. Camera Used: _____

3. What photographs were completed?

	OD	**OS**
	Required fields including fundus reflex	Required fields including red reflex
	Other; explain _____	Other; explain _____
	_____	_____
	_____	_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

M. Fluorescein Angiography

Complete only at 17 Week visit if a fluorescein angiography was performed at Baseline and is part of usual care.

(A fluorescein angiography should only be performed if part of usual care)

1. Fluorescein Angiography: Date Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy* **OR** ☐ **Not Done**

2. Name of Fluorescein Angiographer: _____ **DRCR ID#:** _____

3. Eyes with Fluorescein Angiography: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

4. Rapid Series Eye: ☐ Right (OD) ☐ Left (OS)

5. Fluorescein Angiography Type: Film Digital

6. Fluorescein Angiography done according to protocol? Yes No

N. Lab Form

	Collection Date	Value	Lab Normal Range (Low Value to High Value)	Not completed but will be completed within 3 weeks.	Missed ?*
HbA1c	___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____	☐	☐

***If missed provide reason in comments section**

O. COMMENTS

P. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

Complete Only After all Other Follow-Up Sections Are Completed

A. Treatment of Study Eye

Complete this section if the Right Eye (OD) is a study eye.

1. Will the right eye be retreated with the randomized treatment? Yes No
(If eye was randomized to injection + laser and will be retreated with only one treatment, either peribulbar triamcinolone or laser, please select 'No' and indicate below that the eye will receive a treatment other than the protocol defined treatment.)

a. If 'No, reason *(if more that one reason, select most important reason):*
Max treatment already given
Central Subfield < 250 microns
Eye exhibited substantial improvement
Significant adverse effect of prior treatment
Patient Refuses
Other _____

2. Will the right eye receive a treatment other than the protocol defined treatment? Yes No
If visual acuity in the study eye has decreased by 15 or more letters from baseline (replicated after a repeat refraction), then any treatment may be given at investigator discretion.

Mark all treatments that apply

☐ **Laser Photocoagulation**

☐ **Anterior Peribulbar Triamcinolone Acetonide**

☐ **Posterior Peribulbar Triamcinolone Acetonide**

☐ **Intravitreal Triamcinolone Acetonide**

☐ **Other** _____

3. If the right eye is <u>not</u> being retreated with the randomized treatment, timing of next follow up visit for this eye: _____ [wks/mos]

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

17 Week and 34 Week Visit Form

Complete this section if the Left Eye (OS) is a study eye.

1. Will the left eye be retreated with the randomized treatment? Yes No
(If eye was randomized to injection + laser and will be retreated with only one treatment, either peribulbar triamcinolone or laser, please select 'No' and indicate below that the eye will receive a treatment other than the protocol defined treatment.)

a. If 'No, reason *(if more that one reason, select most important reason):*
Max treatment already given
Central Subfield < 250 microns
Eye exhibited substantial improvement
Significant adverse effect of prior treatment
Patient Refuses
Other _____

2. Will the left eye receive a treatment other than the protocol defined treatment? Yes No
If visual acuity in the study eye has decreased by 15 or more letters from baseline (replicated after a repeat refraction), then any treatment may be given at investigator discretion.

Mark all treatments that apply

☐ **Laser Photocoagulation**

☐ **Anterior Peribulbar Triamcinolone Acetonide**

☐ **Posterior Peribulbar Triamcinolone Acetonide**

☐ **Intravitreal Triamcinolone Acetonide**

☐ **Other** _____

3. If the left eye is <u>not</u> being retreated with the randomized treatment, timing of next follow up visit for this eye: _____ [wks/mos]

.

Were any of the data (other than visual acuity, refraction, and labs) recorded on this form transcribed <u>DIRECTLY</u> from another source (i.e., medical record, surgical notes, patient study worksheet) rather than being confirmed with the patient and directly entered on the website? Yes No

If yes, please fax the source documents to the Jaeb Center for review at 1-800-816-7601.

<u>COMMENTS</u>

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Name of Investigator _____ **DRCR ID#:** _____

Reason for unscheduled visit: **Retreatment Assessment**
Adverse Event
Other; Reason_____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. **Did patient commence or change the usage of any medications since last visit?** ☐ Yes ☐ No
   (If Yes, complete the Concomitant Medication Form.)
2. **Did the patient experience any of the following?** ☐ Yes ☐ No
   If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

B. Study Eye Ocular Treatment Update

RIGHT EYE (OD)

Complete the following if the right eye is a study eye.

1. Has the patient received any treatment for DME in the study right eye since the last visit (i.e. treatment was received at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No

If Yes, explain and provide dates:

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

LEFT EYE (OS)

Complete the following if the left eye is a study eye.

1. Has the patient received any treatment for DME in the study left eye since the last visit (i.e. treatment was received at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No **If Yes, explain and provide dates:**

Visual Acuity

Visual acuity should be measured without cycloplegia or dilation, using the Electronic Visual Acuity Tester at this visit.

Refraction is not required but generally should be performed if there is an unexplained decrease of 15 letters or more since the last refraction.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: ☐ **Not Required or Other**_____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: ☐ **Not Required or Other**_____

Visual Acuity testing date (includes refraction if performed): ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

C. Refraction

Was a refraction performed at this visit prior to initial visual acuity testing? ☐ Yes ☐ No

If Yes, Name of Refractionist: _____ **DRCR ID#:** _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

Refraction/ Correction Used: OD _____ (sph) _____ (cyl) @ _____ (axis) ° **OS** _____ (sph) _____ (cyl) @ _____ (axis) °

D. Visual Acuity

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:
☐ Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat
☐ Brightness of screen within range on light meter
☐ Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

ETDRS letter score: OD _____

OS _____

Name of VA Tester: _____ **DRCR ID#:** _____

Was the visual acuity tester masked to the patient's treatment group? Yes No

☐ **Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

E. Repeat Visual Acuity Section (optional)

Refraction and/or repeat visual acuity should be performed in the study eye(s) if there has been an unexplained 15-letter visual acuity loss since the previous refraction.

Was a refraction performed after the initial visual acuity testing in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter refraction and refractionist below:

Name of Refractionist: _____ **DRCR ID#:** _____

Refraction: **OD** _____ (sph) _____ (cyl) @ _____ (axis) o **OS** _____ (sph) _____ (cyl) @ _____ (axis) o

Was visual acuity testing repeated in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter below:

EVA Instrument # *(from label):* _____

ETDRS letter score: OD _____

OS _____

Name of VA Tester: _____ **DRCR ID#:** _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

F. Slit Lamp Exam

A slit lamp exam is optional, but should be performed if:

- **Assessment for retreatment will be performed.**
- **Investigator determines slit lamp exam is warranted.**

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Slit lamp exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

RIGHT EYE (OD)

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

LEFT EYE (OS)

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

G. Intraocular Pressure Measurement

Intraocular pressure measurement is optional, but should be performed if:

- **Assessment for retreatment will be performed.**
- **Investigator determines slit lamp exam is warranted.**

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

IOP measurement date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

IOP Tester: _____

G1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*	**Right eye (OD)?**	Yes	No
	Left eye (OS)?	Yes	No

G2. IOP Measurement

RIGHT EYE (OD)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

LEFT EYE (OS)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP

Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is >= 30 mmHg at one visit or >25 mm Hg for 17 Week or more. The treatment to prescribe will be at investigator's discretion and may include referral to another ophthalmologist.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

H. Lens Assessment

(See procedure manual for lens assessment procedure)

A lens assessment exam is optional, but should be performed if:

- **Assessment for retreatment will be performed.**
- **Investigator determines slit lamp exam is warranted.**

Will a lens assessment be performed on the RIGHT eye at this visit? **Yes** **No**

If No, reason: _____

Will a lens assessment be performed on the LEFT eye at this visit? **Yes** **No**

If No, reason: _____

Lens assessment date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

RIGHT EYE (OD)

1. Lens Status ☐ Phakic ☐ Pseudophakic ☐ Aphakic

If Phakic, complete the following:

2. Nuclear sclerosis
(see procedure manual for standard photos) ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

3. Posterior subcapsular cataract
(see procedure manual for standard photos) ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

4. Cortical cataract
(see procedure manual for standard photos) ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

5. If lens opacity(ies) present, estimated effect on visual acuity ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

If Pseudophakic or Aphakic, complete the following:

6. Posterior capsular opacity? ☐ Yes ☐ No

7. If Yes, estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

LEFT EYE (OS)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

I. Fundus Exam

A dilated fundus exam is optional, but should be performed if:

- **Assessment for retreatment will be performed.**
- **Investigator determines slit lamp exam is warranted.**

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Dilated fundus exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

RIGHT EYE (OD)

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

LEFT EYE (OS)

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

J. OCT

OCT is optional, but should be performed if:

- **Assessment for retreatment will be performed.**
- **Investigator determines slit lamp exam is warranted.**

Will OCT be performed on the RIGHT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

Will OCT be performed on the LEFT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

1. Date OCT Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

2. Time OCT Performed: _____ : _____ am/ pm

3. OCT Technician: _____

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

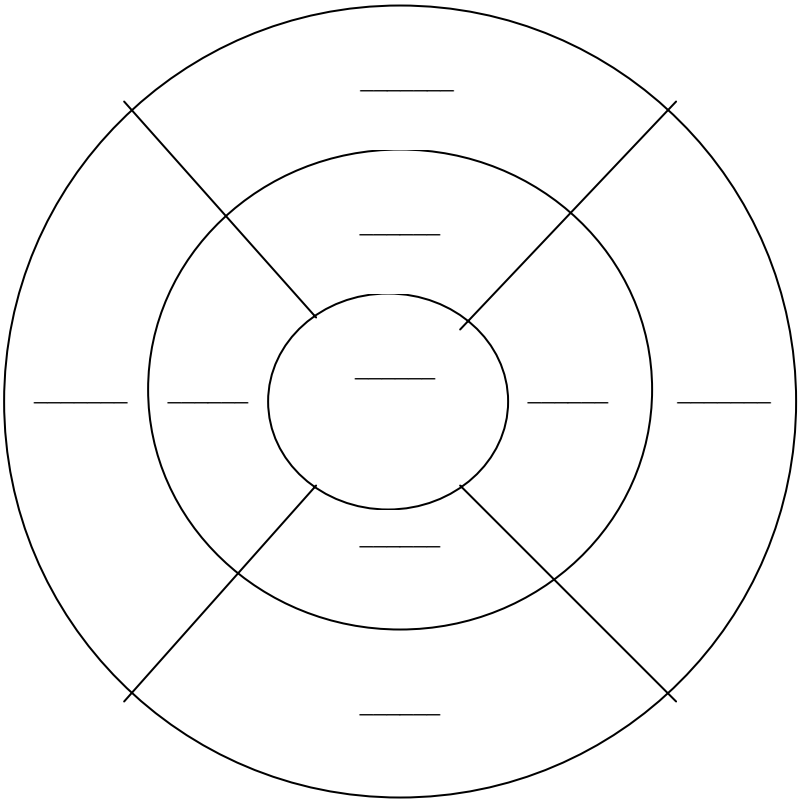
Unscheduled Visit Form

Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

RIGHT EYE (OD)

OCT is required on the right eye

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(IF OCT 3 Version 4 was used please enter signal strength)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

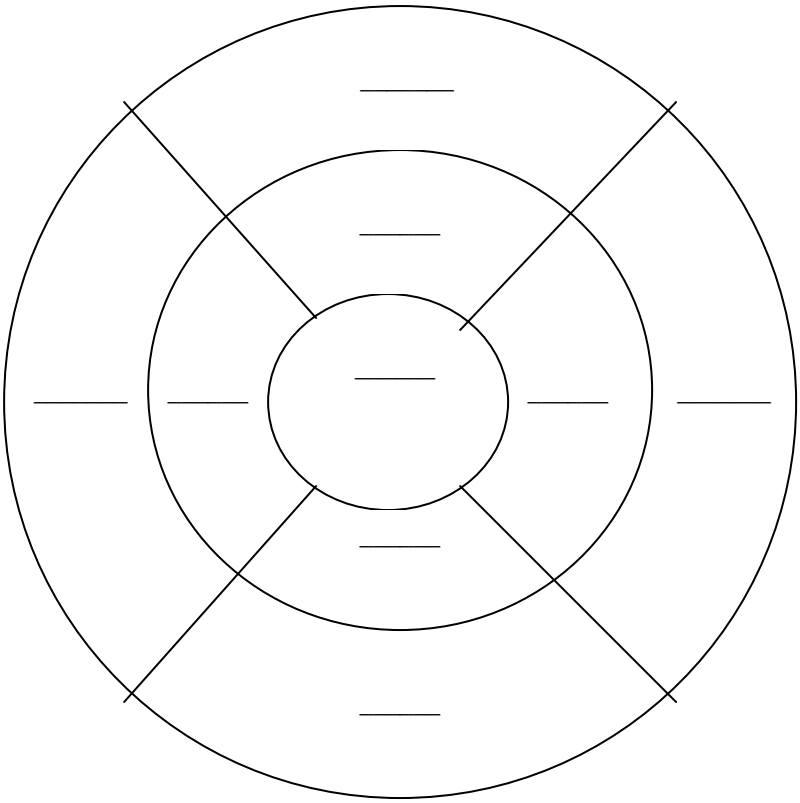
Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

LEFT EYE (OS)

OCT is required on the left eye

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(IF OCT 3 Version 4 was used please enter signal strength)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

N. COMMENTS

O. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

Complete Only After all Other Follow-Up Sections Are Completed

A. Treatment of Study Eye

Complete this section if the Right Eye (OD) is a study eye.

1. Will the right eye be retreated with the randomized treatment? Yes No
(If eye was randomized to injection + laser and will be retreated with only one treatment, either peribulbar triamcinolone or laser, please select 'No' and indicate below that the eye will receive a treatment other than the protocol defined treatment.)

a. If 'No, reason *(if more that one reason, select most important reason):*

Max treatment already given
Central Subfield < 250 microns
Eye exhibited substantial improvement
Significant adverse effect of prior treatment
Patient Refuses
Other _____

2. Will the right eye receive a treatment other than the protocol defined treatment? Yes No
If visual acuity in the study eye has decreased by 15 or more letters from baseline (replicated after a repeat refraction), then any treatment may be given at investigator discretion.

Mark all treatments that apply

☐ **Laser Photocoagulation**

☐ **Anterior Peribulbar Triamcinolone Acetonide**

☐ **Posterior Peribulbar Triamcinolone Acetonide**

☐ **Intravitreal Triamcinolone Acetonide**

☐ **Other** _____

3. If the right eye is <u>not</u> being retreated with the randomized treatment, timing of next follow up visit for this eye: _____ [wks/mos]

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Peribulbar Triamcinolone Acetonide Study

Unscheduled Visit Form

Complete this section if the Left Eye (OS) is a study eye.

1. Will the left eye be retreated with the randomized treatment? Yes No
(If eye was randomized to injection + laser and will be retreated with only one treatment, either peribulbar triamcinolone or laser, please select 'No' and indicate below that the eye will receive a treatment other than the protocol defined treatment.)

a. If 'No, reason *(if more that one reason, select most important reason):*
Max treatment already given
Central Subfield < 250 microns
Eye exhibited substantial improvement
Significant adverse effect of prior treatment
Patient Refuses
Other _____

2. Will the left eye receive a treatment other than the protocol defined treatment? Yes No
If visual acuity in the study eye has decreased by 15 or more letters from baseline (replicated after a repeat refraction), then any treatment may be given at investigator discretion.

Mark all treatments that apply

☐ **Laser Photocoagulation**

☐ **Anterior Peribulbar Triamcinolone Acetonide**

☐ **Posterior Peribulbar Triamcinolone Acetonide**

☐ **Intravitreal Triamcinolone Acetonide**

☐ **Other** _____

3. If the left eye is <u>not</u> being retreated with the randomized treatment, timing of next follow up visit for this eye: _____ [wks/mos]

Were any of the data (other than visual acuity, refraction, and labs) recorded on this form transcribed <u>DIRECTLY</u> from another source (i.e., medical record, surgical notes, patient study worksheet) rather than being confirmed with the patient and directly entered on the website? Yes No

If yes, please fax the source documents to the Jaeb Center for review at 1-800-816-7601.

<u>COMMENTS</u>

Peribulbar Triamcinolone Acetonide Study

Adverse Event Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Name of Investigator _____ **DRCR ID#:** _____

A. Description of Event

1. Type of Event: ☐ Systemic ☐ Right Eye (OD) ☐ Left Eye (OS)
(check one)

2. Adverse Event: _____
(Provide a brief description to categorize the event)

3. Date of Onset: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

4. Did this condition exist prior to enrollment? Yes No

5. Intensity (Severity) Mild Moderate Severe
(see definitions below)

6. Is there a reasonable possibility that the event was caused by the study treatment? Yes No
(see definitions below)

7. Does the event meet criteria for a serious adverse event Yes No
(see definitions below)

B. Treatment of Adverse Event

Did patient receive treatment for the Adverse Event? Yes No

If Yes, complete the following:

Surgery: Yes No

If yes, type of surgery _____

Date of surgery: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Medication: Yes No

If yes, list medications here and add details on Concomitant Medication Form

_____

_____

Peribulbar Triamcinolone Acetonide Study

Adverse Event Form

Other: Yes No

If yes, detail _____

_____

C. Outcome

1. Outcome: Ongoing Complete Recovery Recovered with sequelae Fatal

2. Date of Resolution: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy* **OR** ☐ **Ongoing**

D. Additional Information for Serious Adverse Event

1. Weight: _____ **lbs / kgs** **OR** ☐ Not available

2. Outcomes Attributed to the Serious Adverse Event: *(check all that apply)*

☐ Death (date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyy*)
☐ Congenital Anomaly
☐ Life Threatening
☐ Required Intervention to prevent permanent impairment/damage
☐ Hospitalization -- initial or prolonged
☐ Disability
☐ Other _____

3. Provide detailed description of the event
(see definitions below)

_____
_____
_____

4. Relevant Tests/Laboratory Data (including dates)? Yes No
(see definitions below)

If 'Yes', list: _____
_____
_____

Peribulbar Triamcinolone Acetonide Study

Adverse Event Form

5. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)**?** Yes No
(see definitions below)

If 'Yes', detail: _____

_____

_____

6. Concomitant medical products and therapy dates (exclude treatment of event)? Yes No
(see definitions below)

If 'Yes', please explain: _____

_____

_____

COMMENTS

Intensity (Question A.5)

Mild - Symptom(s) barely noticeable to subject or does not make subject uncomfortable; does not influence performance or functioning; prescription drug not ordinarily needed for relief of symptom(s).

Moderate - Symptom(s) of sufficient severity to make subject uncomfortable; performance of daily activity is influenced; subject is able to continue in study; treatment for symptom(s) may be needed.

Severe - Symptom(s) cause severe discomfort; severity may cause cessation of treatment with study medication; treatment for symptom(s) may be given and/or subject hospitalized.

Relationship to Study Treatment (Question A.6)

Reasonable possibility is not the same as “any possibility.” The following should be considered when evaluating the relationship:

- Timing of event
- Patient’s history
- Prevalence of finding in population at risk
- Other possible causes - diseases, exposures, therapies, etc
- Known pharmacology of study drug (and control)

Peribulbar Triamcinolone Acetonide Study

Adverse Event Form

Serious Adverse Event (Question A.7)

Any adverse event that meets one or more of the following criteria:

1 - Results in death
2 - Is life threatening
3 - Requires inpatient hospitalization or prolongation of existing hospitalization
4 - Results in persistent or significant disability/incapacity
5 - Is a congenital anomaly/birth defect.

Detailed description of the event (Question D.3)

Describe the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution), fax copies of these records with any confidential information deleted to the Jaeb Center at 1-800-816-7601. DO NOT identify any patient, physician, or institution by name.

Relevant Tests/Laboratory Data (Question D.4)

Provide all appropriate information, including relevant *negative* test and laboratory findings, in order to most completely convey how the medical work-up/assessment led to strong consideration of medical-product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated.

Include:

- Any relevant baseline laboratory data prior to the administration or use of the medical product/study procedure
- All laboratory data used in diagnosing the event
- Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

If available, include:

- Any pre- and post-event medication levels and dates (if applicable)
- Synopses of any relevant autopsy, pathology, engineering, or lab reports

If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted. DO NOT identify any patient, physician or institution by name.

Other relevant history, including preexisting medical conditions (Question D.5)

If available and applicable, provide information on:

- Other known conditions in patient, e.g., *Hypertension, Diabetes mellitus, Renal/hepatic dysfunction, etc.)*
- Significant history
  - *Race*
  - *Allergies*
  - *Pregnancy history*
  - *Smoking and alcohol use*
  - *Drug abuse, etc.*

Concomitant medical products and therapy dates (Question D.6)

List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at the time of the event. DO NOT include products used to treat the event.