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

Eye being assessed for eligibility: _____

Vitrectomy Study

Enrollment Form

Assign an 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 signed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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

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

Indicate study eye? ☐ Right (OD) ☐ Left (OS)

Note: Subject can have only one study eye. If both eyes are to have a vitrectomy, the first eye to have the vitrectomy will be the study eye.

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

Eye being assessed for eligibility: _____

Vitrectomy Study

Enrollment Form

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

A. Eligibility Checklist

(All boxes must be checked for patient eligibility)

Note: An Eligibility criterion refers to the eye being evaluated for the study.

- ☐ **1. Patient is having a vitrectomy in the study eye for DME.**
- ☐ **2. Definite retinal thickening due to DME present in the study eye based on clinical exam involving the center of the macula.**
- ☐ **3. Visual acuity in the study eye is ≥ 20/800 on office testing and is expected to improve if macular edema resolves.**
  Note: If E-ETDRS testing has not yet been completed, visual acuity will need to be ≥ 3 letters when it is done.
- ☐ **4. Presence of vitreomacular traction in the study eye associated with macular edema OR edema is felt to be too diffuse to respond to focal or grid laser OR edema judged to be inadequately responsive to previous treatment(s) and unlikely to benefit from further focal photocoagulation**
- ☐ **5. No prior pars plana vitrectomy in the study eye.**
- ☐ **6. (1) Media clarity in the study eye, (2) pupillary dilation of the study eye, and (3) patient cooperation sufficient for adequate fundus photos.**
- ☐ **7. Macular edema in the study eye is not due to a condition other than diabetic macular edema (e.g., cataract extraction) and there is no 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, post surgical cystoid macular edema, etc.).**
- ☐ **8. There is no ocular condition present in the study eye such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g., foveal atrophy, pigmentary abnormalities, subfoveal hard exudates, fibrous metaplasia, nonretinal condition)**
- ☐ **9. No major ocular surgery in the study eye (including cataract extraction, scleral buckle, any intraocular surgery, etc.) within 6 months prior to enrollment and none anticipated within the next 6 months following enrollment.**
- ☐ **10. The study eye does NOT have a history of YAG capsulotomy within 2 months prior to enrollment.**
- ☐ **11. No treatment of DME in study eye in prior 3.5 months, including macular photocoagulation and intravitreal/peribulbar corticosteroid injections.**
- ☐ **12. Peripheral scatter photocoagulation on the study eye not performed in prior 4 months and not expected to be needed within 4 months following enrollment.**
- ☐ **13. Patient does not have a condition (medical, social) that would preclude participation in the study (e.g., unstable medical status including blood pressure and glycemic control).**
- ☐ **14. Blood pressure <= 180/110 (systolic <= 180 and diastolic <= 110)**
- ☐ **15. Patient not expecting to move out of the area of the clinical center to an area not covered by another clinical center during the next year.**

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

Eye being assessed for eligibility: _____

Vitrectomy Study

Enrollment Form

B. 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: _____

C. 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 or ☐ 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*

D. Prior Treatment of Diabetic Retinopathy in the Study Eye

For eligibility, no treatment for macular edema can be received in the eye being evaluated for the study within 3.5 months prior to enrollment and peripheral scatter photocoagulation cannot be done within 4 months prior to enrollment.

1. Has the study eye been previously treated for DME (>=3.5 mos ago)? ☐ Yes ☐ No
If YES, check all that apply:

- ☐ **a. Macular photocoagulation**
- ☐ **b. Intravitreal corticosteroids**
- ☐ **c. Peribulbar corticosteroids**
- ☐ **d. Other treatment for DME _____**

2. Has the study eye received peripheral scatter photocoagulation (≥ 4 mos ago)? ☐ Yes ☐ No

Comments

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.

E. Visual Acuity of Study Eye

Test visual acuity of each eye without cycloplegia or dilation using Electronic ETDRS protocol. If eye is dilated prior to E-ETDRS testing, please allow at least 30 minutes between the time of the last ocular exam or imaging procedure and the E-ETDRS visual acuity test. Testing a dilated eye will be a protocol deviation.

Protocol refraction and visual acuity are is required on the study eye. If refraction and or visual acuity are performed on the nonstudy eye, it may be recorded.

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 21 days prior to surgery.

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

1a. If Yes, record the correction for the study eye:

OD _____ _____ @ _____ o **OS** _____ _____ @ _____ o

sph cyl axis sph cyl axis

1. Visual Acuity testing date (includes refraction): __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

(Completion within 8 days prior to surgery is preferred. However, testing within 21 days of surgery is acceptable.)

2a. Was the eye dilated prior to refraction/electronic visual acuity testing? Yes No

(Note: E-ETDRS acuity should be measured prior to dilation. If necessary to avoid an extra patient visit, acuity may be tested 30 minutes after the last exam or imaging procedure. This will be a protocol deviation.)

2b. If Yes, please select time from last exam or imaging procedure to visual acuity measurement.

< 30 minutes 30 – 60 minutes > 60 minutes

3. Refraction: OD _____ _____ @ _____ o **OS** _____ _____ @ _____ o

sph cyl axis sph cyl axis

4. Name of Refractionist: _____ DRCR ID#: __ __ __ - __ __ __

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

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

Calibration Checks

Verify the following:

☐ **6**. Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat

☐ **7**. Brightness of screen within range on light meter

☐ **8**. Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

9. E-ETDRS letter score: OD _ _____ (required study eye only) **OS** _ _____(required study eye only)

To qualify as a study eye, visual acuity score must be ≥ 3 letters (approximately 20/800 or better)

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

(If vision is too poor to perform E-ETDRS visual acuity test, please enter acuity score of 0 for that eye)

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

Vitrectomy Study

Enrollment Form

Comments

F. Slit Lamp Exam of the Study Eye

Slit Lamp Exam is required on the study eye

Slit Lamp Exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
(Must be within 21 days prior to surgery.)

1. **Abnormality potentially producing VA of 20/40 or worse on study eye:** ☐ None
   (Check all that apply)
   ☐ Cornea
   ☐ Anterior Segment (other than lens)
   ☐ Other: _____

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

G. Intraocular Pressure of Study Eye

IOP measurement is required on the study eye.

IOP Exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
(Must be within 21 days prior to surgery.)

1. **Does patient have a history of ocular hypertension in his/her study eye? Yes No**

   If YES, what treatment is currently prescribed? None/1 topical med/>1 topical med

2. **IOP Tester _____**
3. **Intraocular Pressure ofstudy eye: _____ mm Hg** *(Using Goldmann Tonometer)*

Comments

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.

H. Lens Assessment of Study Eye

Lens assessment is required on the study eye.

Lens Assessment Exam Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be within 21 days prior to surgery.)

1. Lens Status	☐ 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

I. Fundus Exam of Study Eye

Complete this section for the study eye

Dilated Fundus Exam Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be within 21 days prior to surgery.)

1. Epiretinal Membranes Present: ☐ No ☐ Probable ☐ Definite ☐ Cannot determine

2. Status of vitreous: ☐ Attached ☐ Detached ☐ Partially attached ☐ Uncertain

2a. If vitreous partially attached, specify location: ☐ Disc ☐ Macula ☐ Entire posterior pole

3. Abnormality potentially producing VA of 20/40 or worse: ☐ None
(Check all that apply)
☐ Vitreous
☐ Retina/ choroid (other than diabetic retinopathy)
☐ Optic nerve (includes glaucoma)
☐ Other: _____

4. Estimate duration of DME at enrollment: ☐ < 6 months ☐ 6-12 months ☐ > 12 months

5. Reason for vitrectomy:
(Check all that apply)
☐ Vitreomacular interface abnormality/traction
☐ Unresponsive to other therapies
☐ Other: _____

Comments

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.

OCT

OCT 3 or higher must be used.

OCT measurement is required for the study eye.

1. OCT: Date Performed: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
(Must be within 21 days prior to surgery.)

2. OCT: Time Performed: _____:_____ AM/PM

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

4. Was OCT 3 or higher used? Yes No

If Yes, select version: OCT3 (version < 4) OCT3 (version 4)

If No, reason: _____

Note: Standard deviation should be <= 10% of the center point thickness and, if using OCT3 version 4, signal strength should be >= 6 for an adequate OCT scan. If either of these two criteria are not met, the scans may be submitted if the OCT technician believes that the scans are of adequate quality.

5. Thickness of the central subfield on OCT: Study Eye _____ microns

6. Thickness of the center point +/- standard deviation: Study Eye _____ +/- _____ microns

7. Signal Strength ***(if OCT 3 Version 4 was used please enter signal strength)***: _____

Comments

FUNDUS PHOTOGRAPHY

Fundus photos are required on the study eye.

1a. ETDRS Fundus Photos: Date Performed (7-fields and Fundus (Red) Reflex):

___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Must be performed in both eyes within 21 days prior to surgery.

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

1c. Camera Used: _____

2. Was a fluorescein angiogram performed? ☐ Yes ☐ No

(If Yes, please complete the fluorescein angiogram form)

Comments

FLUORESCEIN ANGIOGRAPHY

(Only perform fluorescein angiography on the study eye if part of usual care)

1. Fluorescein Angiography:
Date Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
Must be performed within 21 days prior to surgery

1a. Fluorescein Angiographer ID: __ __ __ - __ __ __

1b. Fluorescein Angiography Type: Film Digital

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

Comments

HbA1c

Lab testing does not need to be repeated if HbA1c and lab normal values are available from within the prior 3 months. If not available at the time of enrollment, test may be obtained within 3 weeks after enrollment.

	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**

Comments

Vitrectomy Surgery Form for the Study Eye

Vitrectomy Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ *dd/MMM/yyyy*
Name of Investigator

Vitrectomy Surgery form for the study eye

Eye Treated: OD OS

Surgical Procedure

1. What gauge vitrectomy system was used? 19/20 gauge 25 gauge other_____
2. Was the posterior hyaloid removed? Yes No
3. Was the posterior hyaloid peeled from macula? Yes No
4. Was peripheral vitreous removed, leaving only a small residual vitreous skirt? Yes No
5. Was an epiretinal membrane peeled? Yes No
6. Was the internal limiting membrane removed? Yes No

   6a. If 'Yes', what was the diameter of the ILM circle peeled? _____microns

7. Were agents used to improve visualization of membranes? Yes No

   7a. If Yes, please select all the agents used:

   - ☐ Triamcinolone acetonide
   - ☐ Indocyanine Green - Concentration used_____%
   - ☐ Trypan Blue
   - ☐ Other _____

8. Was laser used? Yes No

   8 a. If 'Yes', indicate the type of laser (check all that apply):

   - ☐ Focal to break(s)
   - ☐ PRP
   - ☐ Focal macular
   - ☐ With edoprobe
   - ☐ With LIO
   - ☐ Other_____

   8b. If 'Yes', indicate the number of spots administered: # spots_____

9. Was peripheral cryotherapy given? No Yes, not treated for breaks Yes, treated for breaks

   9a. If 'Yes' was air or gas tamponade used? Yes No

   9b. If 'Yes' specify type: ☐ Air ☐ SF_6 (%) ☐ C_3F_8

10. Were corticosteroids used at the close of the procedure? Yes No

10a. If 'Yes' dose:

10b. If 'Yes', please choose the route (select all that apply):

- ☐ Intravitreal
- ☐ Peribulbar
- ☐ Subtenon's
- ☐ Subconjunctival
- ☐ Intravenous

11. Was the lens removed? Yes No

11a. If 'Yes', please select the technique:

Pars plana lensectomy Phacoemulsification Other _____

12. Was an IOL implanted? Yes No

12a. If 'Yes', select type of IOL implanted:

PC IOL in bag
AC IOL
Other_____

13. Was posterior capsulotomy performed? Yes No

14. Record the total operating time: _____ hr _____ min

Intraoperative Findings:

1. Epiretinal Membranes Present ☐ No ☐ Probable ☐ Definite ☐ Cannot determine Not Evaluated

2. Status of vitreous ☐ Attached ☐ Detached ☐ Partially Detached ☐ Uncertain

2a. If vitreous partially attached, specify location ☐ Disc ☐ Macula ☐ Entire posterior pole

Operative Complications

1. Did the patient experience any of the following complications from the vitrectomy? Yes No

1a. If 'Yes' please describe where appropriate below

- ☐ Anesthesia complications
- ☐ Surgical Complications

COMMENTS

Record any pertinent information about the procedure that is not covered above

J. Complete Enrollment

1. **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.**
2. **Has the Patient Contact Information Form been completed?** Yes No
   Must be YES before patient can be enrolled.
   Fax Form to the Jaeb Center at **1-800-816-7601.**
3. **Has a study investigator verified the patient's eligibility?** Yes No
   Must be YES for patient eligibility.
4. **Name of Investigator _____ DRCR ID#: _____**

Comments

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: ___ ___ ___ ___ -___ ___ ___ ___ Namecode: ____ ____ ____ ____ ____

Study Eye: _____

Vitrectomy Study

Follow-Up Visit Form

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

Visit: _____

Investigator: _____

A. MEDICAL UPDATE

Date Medical Update Elicited: **If not today, enter date:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Please review any visits since the prior visit.

1. Did the patient experience any postoperative complications or unexpected adverse events as a result of the vitrectomy (not reported on a previous case report form)? Yes No
(If Yes, select all that apply and enter data of diagnosis)

- ☐ **Vitreous Hemorrhage** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Development of Additional Vitreomacular Interface Abnormalities** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Elevated IOP Requiring Treatment** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Retinal Detachment** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Retinal Tear** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Endophthalmitis** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Macular Ischemia** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Double Vision** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Other** _____ ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Other** _____ ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Other** _____ ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Complete questions 2a and 2b at 3 month visit only

2a. Was intravitreal steroid injection administered (within 1 week post op)? Yes No

2b. Was periocular steroid injection administered (within 1 week post op)? Yes No

2c. Has the patient's right/left study eye received any treatment for DME since the vitrectomy/ prior protocol visit (not reported on a previous case report form)? Yes No
(If Yes, select all that apply and enter data of treatment)

- ☐ **Intravitreal Steroid** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Peribulbar Steroid** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Focal Laser** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Other** _____ ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Vitrectomy Study

Follow-Up Visit Form

3. Has the patient's right/left study eye received an ocular intervention for a reason other than DME since the vitrectomy/ prior protocol visit (not reported on a previous case report form)? Yes No

(If Yes, select all that apply and enter data of treatment)

- ☐ **Panretinal Photocoagulation** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Cataract Surgery** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Other** _____ ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
- ☐ **Other** _____ ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

COMMENTS

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.

Vitrectomy Study

Follow-Up Visit Form

B. VISUAL ACUITY

Refraction and visual acuity is required at this visit in the right/left study eye. If refraction and or visual acuity is performed on the nonstudy eye it may be recorded.

Test visual acuity 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): __ __ / __ __ __ / __ __ __ __ ***dd/MMM/yyyy***

1. Was a refraction performed at this visit prior to visual acuity testing in either eye?

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

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

8. E-ETDRS letter score: OD _____ **OS** _____

(If vision is too poor to perform E-ETDRS visual acuity test, please enter acuity score of 0 for that eye)

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

☐ **10. Acuity testing completed but testing procedure deviated from protocol (check here if ETDRS charts were used).**

Please detail _____

Vitrectomy Study

Follow-Up Visit Form

COMMENTS

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.

Vitrectomy Study

Follow-Up Visit Form

C. SLIT LAMP

Perform IOP and slit lamp on study eye only at each follow up visit

Slit Lamp Exam is Required on the Right/left study Eye

Will a slit lamp exam be performed in the right/left study eye at this visit? Yes No

If No, reason: _____

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

1. Abnormality potentially producing VA of 20/40 or worse:

(Check all that apply)

- ☐ None
- ☐ Cornea
- ☐ Anterior segment (other than lens)
- ☐ Other _____

2. Iris neovascularization:

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

D. IOP

IOP measurement is required on the right/left study eye.

Will an intraocular pressure measurement be performed in the right/left study eye at this visit? Yes No

If No, reason: _____

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

1. Is patient currently on IOP lowering medication for the right/left study eye: ☐ **Yes** ☐ **No**

2. IOP Tester _____

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

(Using Goldmann Tonometer)

Vitrectomy Study

Follow-Up Visit Form

COMMENTS

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.

Vitrectomy Study

Follow-Up Visit Form

E. LENS ASSESSMENT

Perform lens assessment and dilated fundus exam on the study eye only at each follow-up visit

Lens assessment is required on the right/left study eye.

Will a lens assessment be performed the in right/left study eye at this visit? Yes No

If No, reason: _____

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

1. Lens Status	☐ 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

Vitrectomy Study

Follow-Up Visit Form

F. Dilated Fundus

Dilated Fundus Exam is required on the right/left study eye.

Will a dilated fundus exam be performed in the right/left study eye at this visit? **Yes** **No**

If No, reason: _____

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

1. Abnormality potentially producing VA of 20/40 or worse: *(Check all that apply)*

- ☐ None
- ☐ Vitreous
- ☐ Retina/ choroid (other than diabetic retinopathy)
- ☐ Optic nerve (including glaucoma)
- ☐ Other _____

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

3. Epiretinal Membranes Present:

☐ No ☐ Probable ☐ Definite ☐ Cannot determine

4. Residual vitreous attached to posterior pole
(If retinal detachment occurred, please indicate in the Major Exam Findings Section):

☐ No ☐ Yes, traction present ☐ Yes, no traction present

MAJOR EXAM FINDINGS

Major Exam Findings:

Where there any major ocular exam findings? ☐ **Yes** ☐ **No**

If Yes, Check all that apply:

- ☐ Corneal Ulcer
- ☐ Vitreous Hemorrhage
- ☐ Retinal Detachment
- ☐ Macular Ischemia
- ☐ Phthisis
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____

Vitrectomy Study

Follow-Up Visit Form

COMMENTS

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.

Vitrectomy Study

Follow-Up Visit Form

G. OCT

Perform OCT on the study eye at each follow-up visit

OCT measurement is required for the right/left study eye.

OCT 3 or higher must be used.

Will OCT be performed on the right/left study eye at this visit? Yes NO

If No, reason: _____

1. **OCT: Date Performed: Enter date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ ***dd/MMM/yyyy***
2. **OCT: Time Performed: _____:_____** AM/PM
3. **OCT Technician ID:** __ __ __ **-** __ __ __
4. **Was OCT 3 or higher used? Yes No**

If Yes, select version: OCT3 (version < 4) OCT3 (version 4)

If No, reason: _____

Note: Standard deviation should be <= 10% of center point thickness and, if using OCT3 version 4, signal strength should be >= 6 for an adequate OCT scan. If either of these two criteria are not met, the scans may be submitted if the OCT technician believes that the scans are of adequate quality or the values are unattainable after repeated scans.

5. **Thickness of the central subfield on OCT:** ____**_____** microns
6. **Thickness of the center point +/- standard deviation:** _____ **+/-** _____ **microns**
7. **Signal Strength** ***(if OCT 3 Version 4 was used please enter signal strength)***: _____

COMMENTS

Vitrectomy Study

Follow-Up Visit Form

H. FUNDUS PHOTOGRAPHY

Fundus photos are will be performed on the right/left study eye at the 6 month, 1 year, 2 year, and 3 year visits.

Will fundus photos be obtained on the right/left study eye at this visit? Yes NO

If No, reason: _____

1a. ETDRS Fundus Photos: Date Performed (7-fields and Fundus (Red) Reflex):
___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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

1c. What photographs were completed? 7-fields and fundus (red) reflex are required for this visit.
Required fields including fundus reflex
Other; explain _____

1d. Camera Used: _____

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ Namecode: ____ ____ ____ ____ ____

Study Eye: _____

Vitrectomy Study

Follow-Up Visit Form

I. HbA1c

Perform only at 1 year, 2 year, and 3 year visits.

	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**

COMMENTS

Vitrectomy Study

Follow-Up Visit Form

J. BLOOD PRESSURE

Perform only at 1 year, 2 year, and 3 year visits.

1. Date blood pressure taken: If not today, enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

☐ **Blood pressure was not taken.**

Reason: _____

2. Blood pressure: _____/_____ mm Hg
(Measure in sitting position after patient has been sitting for at least 5 minutes)

COMMENTS

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.

Vitrectomy Study

Follow-Up Visit Form

K. IMPRESSION/PLAN

1. Will the right/left study eye receive treatment for DME? Yes No
(Laser, steroids, and other treatments for DME generally should not be given until completion of the 6-month exam.)

Mark all treatments that will be given:

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

2. Will the right/left study eye receive panretinal photocoagulation? Yes No

COMMENTS

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.