Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Assign an ID Form

OBTAIN A NEW 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 signed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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

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

ELIGIBILITY

(All boxes must be checked for patient eligibility)

☐ **1. Patient has all of the following in at least one eye:**

(1) Definite retinal thickening due to diabetic macular edema based on clinical exam involving the center of the macula

(2) OCT central subfield >= 225 microns

AND

(3) Pupil dilation to 5 mm or larger.

☐ **2. Blood pressure <= 180/110 (systolic <= 180 and diastolic <= 110)**

☐ **3. No history of renal failure requiring dialysis or renal transplant.**

☐ **4. No Congestive heart failure currently under treatment.**

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Enrollment Form

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

A. DEMOGRAPHIC INFORMATION

1. **Date of Birth:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Enrollment Form

C. PATIENT QUESTIONNAIRE

1. Time patient went to bed last night? _____ am/ pm

2. Time patient arose this morning? _____ am/ pm

3. Did patient sleep with the head of the bed elevated or use 3 or more pillows last night? Yes No

4. History of sleep apnea? Yes No

5. History of Chronic Obstructive Pulmonary Disease (COPD)? Yes No

D. OCULAR PROCEDURE HISTORY

RIGHT EYE (OD)

Complete this section for the Right Eye (OD).

1. Prior treatment for DME in the Right Eye? Yes No

If Yes, check all that apply:

- ☐ **Focal/grid laser photocoagulation in the macula**
- ☐ **Intravitreal Steroid Injection**
- ☐ **Peribulbar Steroid Injection**
- ☐ **Other** _____

2. Previous panretinal scatter photocoagulation in the right eye? No Yes, < 6 mos ago Yes, >= 6 mos ago

3. Previous cataract extraction in the right eye? No Yes, < 6 mos ago Yes, >= 6 mos ago

4. Previous vitrectomy in the right eye? No Yes, < 6 mos ago Yes, >= 6 mos ago

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Enrollment Form

LEFT EYE (OS)

Complete this section for the Left Eye (OS).

1. Prior treatment for DME in the Left Eye? Yes No

If Yes, check all that apply:

- ☐ **Focal/grid laser photocoagulation in the macula**
- ☐ **Intravitreal Steroid Injection**
- ☐ **Peribulbar Steroid Injection**
- ☐ **Other** _____

2. Previous panretinal scatter photocoagulation in the left eye? No Yes, < 6 mos ago Yes, >= 6 mos ago

3. Previous cataract extraction in the left eye? No Yes, < 6 mos ago Yes, >= 6 mos ago

4. Previous vitrectomy in the left eye? No Yes, < 6 mos ago Yes, >= 6 mos ago

E. MEDICATIONS

1. Is the patient currently being medically treated for hypertension (other than diet)? Yes No

2. Please check all applicable medications that the patient is currently taking:

- ☐ **None**
- ☐ **Antihistamines**
- ☐ **ACE inhibitor**
- ☐ **Estrogen**
- ☐ **Beta Blocker**
- ☐ **Topical Eye Drops**
- ☐ **Diuretic**
- ☐ **Glitizones**

COMMENTS

Pt. ID: ___ __ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Exam Form

All OCT measurements must be obtained using the same OCT 3 machine.

1. OCT Serial Number: _____

2. 8 a.m. OCT Measurement 1: OD: _____ **microns**

OS: _____ **microns**

OCT Measurements should be obtained twice in both eyes at each time point

User ID of Primary OCT Operator (Operator performing measurement 1): ___ ___ ___ **-** ___ ___ ___
(The primary OCT operator should remain the same throughout the study)

Protocol Time	Measurement 1			Measurement 2		
	OCT Operator (User ID)	Time	Not Done	OCT Operator (User ID)	Time	Not Done
8 a.m.		_____:_____ am/pm			_____:_____ am/pm	☐
9 a.m.		_____:_____ am/pm	☐		_____:_____ am/pm	☐
10 a.m.		_____:_____ am/pm	☐		_____:_____ am/pm	☐
12 p.m.		_____:_____ am/pm	☐		_____:_____ am/pm	☐
2 p.m.		_____:_____ am/pm	☐		_____:_____ am/pm	☐
4 p.m.		_____:_____ am/pm	☐		_____:_____ am/pm	☐

Note: If any measurements were missed please provide reason in comment section.

BLOOD PRESSURE/ BLOOD GLUCOSE

	8 a.m.	Not Done	12 p.m.	Not Done	4 p.m.	Not Done
Blood Pressure	_____/_____ mmHg	☐	_____/_____ mmHg	☐	_____/_____ mmHg	☐
Blood Glucose	_____ mg/dl	☐	_____ mg/dl	☐	_____ mg/dl	☐

HEIGHT AND WEIGHT

1. Height _____ **inches/centimeters**

2. Weight _____ **lbs/kgs**

Pt. ID: ___ __ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Exam Form

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Visual Acuity Form

Visual Acuity at 8 a.m.

Refraction should be performed while the eye is dilating. After dilation is confirmation (pupil diameter >= 5 mm), recheck the sphere to verify the refraction, and perform the visual acuity.

Test visual acuity of each eye after cycloplegia or dilation using Electronic ETDRS protocol. The eye should be dilated at least 5 mm prior to visual acuity testing.

Corrective Lenses

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

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

Visual Acuity/Refraction

1. Refraction: OD _____ _____ @ _____ o **OS** _____ _____ @ _____ o
sph cyl axis sph cyl axis

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

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

Calibration Checks
Verify the following:

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

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

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

7. Is the pupil dilated at least 5 mm? **Yes** **No**
(If not, do not perform acuity testing until the eye is dilated to at least 5 mm)

8. Time of Testing: _____:_____ am/ pm

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

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

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

_____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Visual Acuity Form

Visual Acuity at 12 noon

Test visual acuity of each eye after cycloplegia or dilation using Electronic ETDRS protocol. The eye should be dilated at least 5 mm prior to rechecking the sphere and testing visual acuity.

Visual Acuity/Refraction

Eyes with visual acuity and refraction at 12 noon: ☐ None ☐Right (OD) ☐Left (OS) ☐ Both (OU)

1. Is the pupil dilated at least 5 mm? Yes No
(If not, do not recheck sphere or perform acuity testing until the eye is dilated to at least 5 mm)

Only the sphere must be rechecked.

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

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

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

5. Time of Testing: _____:_____ am/pm

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

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

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

_____

_____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Visual Acuity Form

Visual Acuity at 4 p.m.

Test visual acuity of each eye after cycloplegia or dilation using Electronic ETDRS protocol. The eye should be dilated at least 5 mm prior to rechecking the sphere and testing visual acuity.

Visual Acuity/Refraction

Eyes with visual acuity and refraction at 4 p.m.: ☐ None ☐Right (OD) ☐Left (OS) ☐ Both (OU)

1. Is the pupil dilated at least 5 mm? Yes No
(If not, do not perform acuity testing until the eye is dilated to at least 5 mm)

Only the sphere must be rechecked.

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

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

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

5. Time of Testing: _____:_____ am/pm

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

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

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

_____

_____

_____

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Fundus Photo Form

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

If fundus photos were obtained within the prior month and no interval treatment for DME has been received, photos do not need to be repeated. Otherwise 3-Field Photos should be obtained on each eye.

Have fundus photos been obtained by the DRCRnet protocol on the RIGHT eye within the prior month and has no treatment for DME been received since the photos were obtained? Yes No

If No, 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_____

Have fundus photos been obtained by the DRCRnet protocol on the LEFT eye within the prior month and has no treatment for DME been received since the photos were obtained? Yes No

If No, 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_____

1. Photographer ID: __ __ __ - __ __ __ ☐ **Photographer not Jaeb Personnel**

2. What photographs were completed?

OD
3-Field
Other; explain _____

_____

OS
3-Field
Other; explain _____

_____

3. Camera Used: _____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

Fundus Photo Form

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___ NameCode: ____ ____ ____ ____ ____ ____

Date: ___ ___ / ___ ___/ ___ ___

OCT Diurnal Variation Study

HbA1c Form

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 the next 3 weeks.

	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
