Laser Photocoagulation for Diabetic Macular Edema

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: ___ ___ / ___ ___ ___ /___ ___ ___ ___

Does the patient have an enucleated eye? Yes No

If 'Yes', indicate eye and describe: Right Eye (OD) Left Eye (OS)
Description: _____

Laser Photocoagulation for Diabetic Macular Edema

Baseline Visit Form

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*

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
See "Personal Census Data" for definitions

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. OCULAR HISTORY

	Right Eye (OD)	Left Eye (OS)
1. Previous focal/grid laser photocoagulation in the macula *must be NO for study eye eligibility*	Yes No	Yes No
2. Other prior treatment for DME? *must be NONE for study eye eligibility* *Please check all that apply*	☐ None ☐ Intravitreal Steroids ☐ Peribulbar Steroids ☐ Laser ☐ Vitrectomy If other, describe: _____	☐ None ☐ Intravitreal Steroids ☐ Peribulbar Steroids ☐ Laser ☐ Vitrectomy If other, describe: _____
3. Previous panretinal scatter photocoagulation *must be NO or ≥ 4 mos ago for study eye eligibility*	No Yes, in prior 4 mos Yes, all Rx ≥ 4 mos ago	No Yes, in prior 4 mos Yes, all Rx ≥ 4 mos ago
4. Previous Nd: YAG laser capsulotomy *must be NO or ≥ 2 mos ago for study eye eligibility*	No Yes, in prior 2 mos Yes, ≥ 2 mos ago	No Yes, in prior 2 mos Yes, ≥ 2 mos ago
5a. Cataract extraction *must be NO or ≥ 6 mos ago for study eye eligibility*	No Yes, <6 mos Yes, ≥6 mos	No Yes, <6 mos Yes, ≥6 mos
5b. Vitrectomy *must be NO or ≥ 6 mos ago for study eye eligibility*	No Yes, <6 mos Yes, ≥6 mos	No Yes, <6 mos Yes, ≥6 mos
5c. Other major intraocular surgery such as glaucoma filter, scleral buckle, cornea transplant *must be NO or ≥ 6 mos ago for study eye eligibility*	No Yes, <6 mos Yes, ≥6 mos	No Yes, <6 mos Yes, ≥6 mos

Laser Photocoagulation for Diabetic Macular Edema

Baseline Visit Form

B. OCULAR HISTORY, Continued

	Right Eye (OD)	Left Eye (OS)
6. Topical ocular treatment currently taking at least 3x/week *Please check all that apply*	☐ None ☐ Antihistamine ☐ NSAID ☐ Steroids ☐ Xalatan ☐ Other glaucoma treatment	☐ None ☐ Antihistamine ☐ NSAID ☐ Steroids ☐ Xalatan ☐ Other glaucoma treatment

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. **Diabetes treatment** *Please select one*
   - None
   - Diet only
   - Insulin
   - Oral
   - Insulin + Oral
3. **If using insulin:**
   a. ☐ **pump or** ☐ **injections** ____**/day (daily average)**
   b. **age when insulin treatment started** ___ ___ yrs old *enter approx age if patient is not precise and records are not available*

D. OTHER MEDICAL HISTORY

1. **Is the patient currently being medically treated for elevated cholesterol/triglycerides (other than diet)?** Yes No
2. **Is the patient currently being medically treated for hypertension (other than diet)?** Yes No
3. **Does the patient have a history of renal failure requiring dialysis or renal transplant?** Yes No
   If Yes, patient is not eligible.
4. **(1) Is the patient in poor glycemic control (in investigator's judgement) or (2) has the patient recently initiated intensive insulin treatment (a pump or multiple daily injections) or plans to do so in the next 3 months?** Yes No
   If Yes, patient is not eligible.
5. **Please check all applicable medications that the patient is currently taking:**

   ☐ **None**

   ☐ **Statin**

   ☐ **ACE inhibitor**

   ☐ **Aspirin** **Dose (per day):** ☐ < 1 adult ☐ 1-7 adult ☐ ≥ 8 adult

   ☐ **Vitamin E** **Dose (mg/day):** ☐ < 40 ☐ 40 - < 600 ☐ ≥ 600 ☐ Unknown

   ☐ **Estrogen**

   ☐ **Diuretic**

E. MISCELLANEOUS

1. **Does the patient have a condition (medical, social) that would preclude participation in the study?** Yes No
   If Yes, patient is not eligible.
2. **Is the patient expecting to move out of the area of the clinical center to an area not covered by another clinical center during the next 12 months?** Yes No
   If Yes, patient is not eligible.

Laser Photocoagulation for Diabetic Macular Edema

Baseline Visit Form

F. VISUAL ACUITY

Visual Acuity Testing Date (includes Refraction): ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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

DRCR ID# of Refractionist: ___ ___ ___ - ___ ___ ___

Test visual acuity of each eye without cycloplegia or dilation using Electronic ETDRS protocol
Refraction must be done on same day as Visual Acuity Testing
Note: The E-ETDRS must be used for Baseline testing on the day of randomization.

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

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 (For EVA/E-ETDRS, transcribe from Palm): OD _____ OS _____
to qualify as a study eye, visual acuity score must be >= 19 letters (approximately 20/400 or better)

DRCR ID# of VA Tester: ___ ___ ___ - ___ ___ ___

G. OPHTHALMIC EXAMINATION

	Right Eye (OD)	Left Eye (OS)
1. Abnormality potentially producing VA of 20/40 or worse *Please check all that apply*	☐ None ☐ Cornea/Anterior segment ☐ Lens ☐ Vitreous ☐ Retina (other than diabetic retinopathy) ☐ Optic nerve (includes glaucoma)	☐ None ☐ Cornea/Anterior segment ☐ Lens ☐ Vitreous ☐ Retina (other than diabetic retinopathy) ☐ Optic nerve (includes glaucoma)
2. Lens *Please select one*	Phakic Pseudophakic Aphakic	Phakic Pseudophakic Aphakic
3. Iris neovascularization *Please select one*	Absent Present	Absent Present

	Right Eye (OD)	Left Eye (OS)
4. Does the patient have definite retinal thickening based on clinical exam at or within 500 microns of the macular center consistent with diabetic macular edema? *must be YES for study eye eligibility*	Yes No	Yes No
5. Is there edema in the macula that is most likely due to a condition other than diabetes such as *cataract extraction or vitreoretinal interface disease (e.g. vitreo-retinal traction or epriretinal membrane)?* *must be NO for study eye eligibility*	Yes No	Yes No
6. Is the patient likely to need panretinal photocoagulation in the next 4 months? *must be NO for study eye eligibility*	Yes No	Yes No

Laser Photocoagulation for Diabetic Macular Edema

Baseline Visit Form

G. OPHTHALMIC EXAMINATION, Continued

	Right Eye (OD)	Left Eye (OS)
7. Does the patient have an ocular condition (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the first 12 months of the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma)? Note: Glaucoma per se is not an exclusion. *must be NO for study eye eligibility*	Yes No	Yes No

H. BLOOD PRESSURE

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

Must be performed within 21 days of randomization

I. OCT & FUNDUS PHOTOGRAPHY

1. On OCT, is the thickness of the central subfield ≥ 250 microns OR, if not, does any one of the 4 subfields directly adjacent to the central subfield have a thickness ≥ 300 microns?

Must be YES for study eye eligibility

Right Eye (OD) ☐ Yes(1) ☐ No(2)

If 'Yes', is there at least one unthickened subfield on OCT? ☐ Yes(1) ☐ No(2)

Left Eye (OS) ☐ Yes(1) ☐ No(2)

If 'Yes', is there at least one unthickened subfield on OCT? ☐ Yes(1) ☐ No(2)

2. Were (1) media clarity, (2) pupillary dilation, and (3) patient cooperation sufficient for adequate fundus photos?

Right Eye (OD) ☐ Yes(1) ☐ No(2) **Left Eye (OS)** ☐ Yes(1) ☐ No(2)

Must be YES for study eye eligibility

J. Randomization

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

Have all signatures and date fields been properly completed on the informed consent form? Yes No
must be YES for study eye eligibility
Fax Signature Page to the Jaeb Center

Has the Patient Contact Information Form been completed? Yes No
must be YES before patient can be randomized
Fax Form to the Jaeb Center

Has a study investigator verified the patient's eligibility? Yes No
must be YES for study eye eligibility

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

Which eye(s) would you like to randomize? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

Laser Photocoagulation for Diabetic Macular Edema

Baseline Visit Form

K. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Baseline Fundus Photography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. FUNDUS PHOTOGRAPHY

1a. ETDRS Fundus Photos: Date Performed (7-fields): ___ ___ / ___ ___ ___ /___ ___ ___ ___ *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. Camera Used: _____

B. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Baseline Fluorescein Angiography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. FLUORESCEIN ANGIOGRAPHY

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

Must be performed within 21 days of randomization

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

B. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Baseline OCT Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. OCT

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

1b. OCT Technician ID: __ __ __ **-** __ __ __

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

B. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Baseline Lab Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

	Missed?			Collection Date	Value	Lab Normal Range (Low Value to High Value)
HbA1c	☐			___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____
BUN	☐			___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____
Creatinine	☐			___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____
LDL	☐	**Fasting?**	Yes No Unknown	___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____
Triglycerides	☐	**Fasting?**	Yes No Unknown	___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____
Microalbumin	☐			___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____

COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Laser Treatment Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

1. Eye to be treated: ☐ Right (OD) ☐ Left (OS)

2. Treatment Group: _____

3. Session # ____ **Sitting #** _____

Retreatment of Patients in Modified-ETDRS Treatment Group

- All retreatment in patients assigned to the modified-ETDRS group, will use the same modified-ETDRS treatment technique.

Retreatment of Patients Mild Macular Grid Treatment Group

- The first retreatment in patients assigned to the MMG group will use MMG limited to only the area of retinal thickening.
- Second and subsequent retreatments in patients assigned to the MMG group will use the modified-ETDRS technique (which allows focal treatment to leaking microaneurysms in the area of retinal thickening).

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

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

3a. Did the eye receive the correct treatment as per the protocol? Yes No

3b. If no, why not? _____

Technique Performed:

4a. Was 50 micron burn size used as per the protocol? Yes No

4b. If no, why not? _____

5. Average Power: _____ **mW**

6. Wave Length: Green Yellow

7. Number of Burns: _____

8. Was the treatment guided by Fluorescein Angiography? Yes No
Should be 'No' for MMG.

9a. Were post treatment field 2stereo photos obtained after treatment? Yes No

9b. If no, why not? _____

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

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

12. Date of next visit: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Post-Laser Fundus Photography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. FUNDUS PHOTOGRAPHY

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

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

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

1d. Camera Used: _____

B. COMMENTS

DRCR-1 Follow-Up Visit Form

Exam Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/mmm/yyyy*

A. OCULAR UPDATE

	Right Eye (OD)	Left Eye (OS)
1. Treatment for DME OTHER THAN THE PROCOCOL FOCAL/GRID PHOTOCOAGULATION since the Last Protocol Visit? *Please check all that apply*	☐ None ☐ Intravitreal Steroids ☐ Peribulbar Steroids ☐ Laser ☐ Vitrectomy ☐ Other If other, describe: _____	☐ None ☐ Intravitreal Steroids ☐ Peribulbar Steroids ☐ Laser ☐ Vitrectomy ☐ Other If other, describe: _____
2. Any of the following procedures done since the Last Protocol Visit?	**Where?** ☐ None ☐ PRP — At Site / Elsewhere ☐ Cataract extraction — At Site / Elsewhere ☐ Nd: YAG laser capsulotomy — At Site / Elsewhere ☐ Vitrectomy — At Site / Elsewhere ☐ Glaucoma filter — At Site / Elsewhere ☐ Scleral buckle — At Site / Elsewhere ☐ Cornea transplant — At Site / Elsewhere ☐ Enucleation — At Site / Elsewhere ☐ Other — At Site / Elsewhere If other, describe: _____	**Where?** ☐ None ☐ PRP — At Site / Elsewhere ☐ Cataract extraction — At Site / Elsewhere ☐ Nd: YAG laser capsulotomy — At Site / Elsewhere ☐ Vitrectomy — At Site / Elsewhere ☐ Glaucoma filter — At Site / Elsewhere ☐ Scleral buckle — At Site / Elsewhere ☐ Cornea transplant — At Site / Elsewhere ☐ Enucleation — At Site / Elsewhere ☐ Other — At Site / Elsewhere If other, describe: _____
3. <u>Topical</u> ocular treatment currently taking at least 3x/week *Please check all that apply*	☐ None ☐ Antihistamine ☐ NSAID ☐ Steroids ☐ Xalatan ☐ Other glaucoma treatment	☐ None ☐ Antihistamine ☐ NSAID ☐ Steroids ☐ Xalatan ☐ Other glaucoma treatment

DRCR-1 Follow-Up Visit Form

B. MEDICAL UPDATE

1. Diabetes treatment *Please select one*
None
Diet only
Insulin
Oral
Insulin + Oral

2. If using insulin: ☐ pump or ☐ injections ____/day (daily average)

3. Is the patient currently being medically treated for elevated cholesterol/triglycerides (other than diet)? Yes No

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

5. Does the patient have a history since the Last Protocol Visit of renal failure requiring dialysis or renal transplant? Yes No

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

☐ **None**
☐ **Statin**
☐ **ACE inhibitor**
☐ **Aspirin Dose (per day):** ☐ < 1 adult ☐ 1-7 adult ☐ ≥ 8 adult
☐ **Vitamin E Dose (mg/day):** ☐ < 40 ☐ 40 - < 600 ☐ ≥ 600 ☐ Unknown
☐ **Estrogen**
☐ **Diuretic**

C. VISUAL ACUITY

Visual Acuity Testing Date (includes Refraction): ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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

DRCR ID# of Refractionist: ___ ___ ___ - ___ ___ ___

Test visual acuity of each eye without cycloplegia or dilation using Electronic ETDRS protocol
Refraction must be done on same day as Visual Acuity Testing

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 (For EVA/E-ETDRS, transcribe from Palm): OD _____ OS _____

DRCR ID# of VA Tester: ___ ___ ___ - ___ ___ ___

☐ **E-ETDRS Visual Acuity not completed in one or both eyes.**

Which Eye? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)
Reason: _____

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

DRCR-1 Follow-Up Visit Form

D. OPHTHALMIC EXAMINATION

	Right Eye (OD)	Left Eye (OS)
1. Any changes indicative of adverse event from laser? *Only complete for Study Eye.* *If 'Yes', complete AE form if not already done.*	Yes No	Yes No
2. Abnormality potentially producing VA of 20/40 or worse *Please check all that apply*	☐ None ☐ Cornea/Anterior segment ☐ Lens ☐ Vitreous ☐ Retina (other than diabetic retinopathy) ☐ Optic nerve (includes glaucoma) ☐ Phthisis	☐ None ☐ Cornea/Anterior segment ☐ Lens ☐ Vitreous ☐ Retina (other than diabetic retinopathy) ☐ Optic nerve (includes glaucoma) ☐ Phthisis
3. Lens *Please select one*	Phakic Pseudophakic Aphakic	Phakic Pseudophakic Aphakic
4. Iris neovascularization *Please select one*	Absent Present	Absent Present

☐ **Ophthalmic exam was not performed.**

Which Eye? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

Reason: _____

Complete the following for the study [right/left] eye at the 3.5 & 8 Month Visits.

5. Status of DME since the Last Protocol visit:
Resolved
Improved but still present
Unchanged
Worse
Recurred (reappearance of DME in previously resolved area)
New (appearance of DME in new area)

6. Does the eye meet criteria for retreatment of DME? Yes No

6a. If 'Yes', will retreatment be given? Yes No

6b. If 'No', reason: pt refuses
max treatment already given
equipment failure
other _____

7. Is any treatment for DME other than the protocol-defined laser treatment to be prescribed/planned? Yes No

7a. If 'Yes', indicate reason and why treatment is being given. _____

_____

_____

Complete the following for the nonstudy [right/left] eye at the 3.5 & 8 Month Visits and for both eyes at 12, 24, 36 Month Visits.

8. Is DME requiring treatment present? Yes No

8a. If 'Yes', what treatment is being prescribed/planned?
☐ None
☐ Intravitreal Steroids
☐ Peribulbar Steroids
☐ Laser
☐ Vitrectomy
☐ Other
If other, describe:
_____

DRCR-1 Follow-Up Visit Form

COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Follow-Up Fundus Photography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. FUNDUS PHOTOGRAPHY

1a. ETDRS Fundus Photos: Date Performed (3-fields): ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

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

1c. Camera Used: _____

1d. What photographs were completed?	**OD**	**OS**
	Required Fields Other	Required Fields Other
	If other, describe: _____	**If other, describe:** _____

☐ **Fundus photos were not completed for one or both eyes.**
Which Eye? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)
Reason photos were not done: Media clarity insufficient
Pupillary dilation insufficient
Patient cooperation insufficient
Equipment failure
Film processing difficulties
Other **If Other, describe:** _____

B. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

12 Month Fluorescein Angiography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. FLUORESCEIN ANGIOGRAPHY

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

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

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

1d. Fluorescein Angiography Type: Film Digital

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

☐ **Fluorescein Angiography was not completed for one or both eyes.**
Which Eye? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)
Reason Fluorescein Angiography was missed: Media clarity insufficient
Pupillary dilation insufficient
Patient cooperation insufficient
Equipment failure
Film processing difficulties
Other **If other, describe:** _____

B. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Follow-Up OCT Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

A. OCT

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

1b. OCT Technician ID: __ __ __ - __ __ __

☐ **OCT was not completed for one or both eyes.**
Which Eye? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)
Reason OCT was not done: Patient cooperation insufficient
Equipment failure
Other **If other, describe:** _____

B. COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Follow Up Lab Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

	Missed?	Collection Date	Value	Lab Normal Range (Low Value to High Value)
HbA1c	☐	___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____

COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

Unspecified Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

Complete this form for a patient exam that is completed at any time other than a protocol-specified visit form. Note: this form does not need to be completed when a patient returns for a laser sitting (which will be recorded on a Laser Treatment Form) unless there is a reason for the visit (e.g., adverse event) that is not related to having laser treatment.

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

2. Reason for Visit:
Ocular Symptoms
Reportable Adverse Event
PRP
Management of Non-Study Eye
Other *If other, complete comment field*

2a. If PRP, Number of Burns: _____

******For a reportable adverse event, complete an Adverse Event Form (see protocol for definition of reportable adverse event)******

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

COMMENTS

Record any information pertinent to the exam and any information you want to have available at the time of the next available protocol visit.

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

Laser Photocoagulation for Diabetic Macular Edema

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#: __ __ __ - __ __ __**

1. Adverse Event: _____

2. Type of Event: Systemic Right Eye (OD) Left Eye (OS) Both Eyes (OU)

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

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

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

6. Intensity (Severity): Mild Moderate Severe ***See below for definitions***

7. Relationship to Study Procedure: Possibly Probably Definitely ***See below for definitions***

8. Action Taken (i.e., medical or surgical intervention): Yes No
If yes, describe: _____

_____

9. Outcome: Ongoing Complete Recovery Recovered with sequelae Fatal ***See below for definitions***

10. Does the event meet criteria for a serious adverse event? Yes No

COMPLETE BELOW FOR SERIOUS ADVERSE EVENT

11. Weight: _____ **lbs / kgs**

12. 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 _____

13. Describe event or problem (provide detailed description of the event):

_____

_____

_____

14. Relevant Tests/Laboratory Data (including dates)? Yes No ***See below for definitions***

If 'Yes', please explain: _____

_____

_____

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

If 'Yes', please explain: _____

16. Concomitant medical products and therapy dates (exclude treatment of event)? Yes No
See below for definitions

If 'Yes', please explain: _____

COMMENTS

Definitions by Question

6. **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.

7. **Possibly** - Any reaction that does not follow a reasonable temporal sequence from administration of study medication/procedure OR that is likely to have been produced by the subject's clinical state or other modes of therapy administered to the subject.

   Probably - A reaction that follows a reasonable temporal sequence from administration of study medication/procedure AND that could not be reasonably explained by the known characteristics of the subjects clinical state or other modes of therapy administered to the subject.

   Definitely - A reaction that follows a reasonable temporal sequence from administration of study medication/procedure AND that follows a known response pattern to the suspected drug AND that recurs with rechallenge, and/or is improved by stopping the drug, reducing the dose or discontinuing the procedure.

10. 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.

13. 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

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synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution), attach copies of these records with any confidential information deleted. DO NOT identify any patient, physician, or institution by name.

14. 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.
15. If available and applicable, provide information on:
    - Other known conditions in the patient, e.g., (*Hypertension, Diabetes mellitus, Renal/hepatic dysfunction, etc.)*
    - Significant history
        - *Race*
        - *Allergies*
        - *Pregnancy history*
        - *Smoking and alcohol use*
        - *Drug abuse, etc.*
16. 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.

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

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Patient Final Status Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

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

REASON FOR CHANGE OF PATIENT STATUS TO INACTIVE provide pertinent details in COMMENTS

Select only one reason:

_____ Patient does not meet eligibility criteria for randomization

_____ Patient request to withdraw

_____ Lost to follow up *Preapproval by Jaeb Center required prior to classifying a patient as lost to follow up*

_____ Site withdraws patient *Preapproval by Jaeb Center required prior to withdrawing patient*

_____ Death Date of Death ___/___/___ Cause of Death _____

_____ Other ***Preapproval by Jaeb Center required***

COMMENTS