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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

OBTAIN A STUDY ID FOR A NEW PATIENT

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 eligible, the investigator will select one to be the study eye.

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

ELIGIBILITY/MEDICAL HISTORY SECTION

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

PRP Treatment Regimen

This eye is designated to receive either 1 treatment sitting or 4 treatment sittings (see definition below) to complete the scatter treatment. If the investigator does not want to completely treat the eye in designated number of sittings, this eye should not be enrolled.

- **1 PRP sitting regimen:** 1 sitting with a minimum of 1200 to a maximum of 1600 burns.
- **4 PRP sitting regimen:** 4 sittings, with approximately 300 burns in each of the first two sittings and investigator judgment for the number of burns for the 3rd and 4th sittings as long as the total for the four sittings is at least 1200 to 1600 burns.

Is it anticipated that the scatter treatment will be completed in 1 treatment sitting/ 4 treatment sittings as predetermined by the investigator? Yes No

(Must be yes to enroll patient)

A. ELIGIBILITY CHECKLIST *(All boxes must be checked for patient eligibility)*

Note: All ocular eligibility refers to the eye being evaluated for the study.

- ☐ **1. Study eye has presence of early proliferative or severe nonproliferative diabetic retinopathy for which investigator intends to perform full scatter photocoagulation in the pre-specified number of sittings.**
- ☐ **2. Center point retinal thickness in right/left study eye measured on OCT <= 200 microns.**
- ☐ **3. No prior scatter photocoagulation in the right/left study eye.**
- ☐ **4. Retinopathy in the right/left study eye is not high risk (i.e. not severe proliferative)**
- ☐ **5. (1) Media clarity in the study eye, (2) pupillary dilation of the study eye, and (3) patient cooperation sufficient for adequate fundus photos and OCT and to administer full scatter photocoagulation.**
- ☐ **6. No ocular condition present (other than diabetes) that, in the opinion of the investigator, might produce macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome, significant vitreomacular interface disease, etc.).**
- ☐ **7. No major ocular surgery in the right/left study eye (including cataract extraction, scleral buckle, any intraocular surgery, etc.) within 6 months prior to enrollment and none anticipated within the next 8 months following enrollment.**

☐ **8. The study eye does NOT have a history of YAG capsulotomy within 2 months prior to enrollment.**

☐ **9. No treatment for DME in the right/left study eye in prior 6 months, including focal/grid macular photocoagulation and corticosteroids by any route.**

☐ **10. No treatment for DME in the right/left study eye is planned.**

☐ **11. Patient does not have a history of pancreatic transplant or chronic renal failure requiring dialysis or kidney transplant.**

☐ **12. 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).**

☐ **13. 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.**

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: _____

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

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. CURRENT MEDICATION

1. **Please check all applicable medications that the patient is currently taking:**
   - ☐ **None**
   - ☐ **Antihypertensive**
   - ☐ **ACE inhibitor**
   - ☐ **Arthritis medication**
   - ☐ **Beta Blockers**
   - ☐ **Diuretic**

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

E. PRIOR TREATMENT IN STUDY EYE

1. Has the right/left study eye been previously treated for DME (>=6 mos ago)? ☐ Yes ☐ No
Note: For eligibility, no treatment for macular edema can be received within 6 months prior to enrollment.

If YES, check all that apply:

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

2. Has a major ocular surgery been performed on the right/left study eye (>= 6 mos ago)? ☐ Yes ☐ No
Note: For eligibility, no major ocular surgery can be performed within 6 months prior to enrollment.

If YES, check all that apply:

- ☐ **a. Cataract extraction**
- ☐ **b. Scleral buckle**
- ☐ **c. Intraocular surgery**
- ☐ **d. Other major ocular surgery** _____

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: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

F. VISUAL ACUITY

Test visual acuity of both eyes without cycloplegia or dilation using Electronic ETDRS protocol. Protocol refraction is required on the right/left study eye. If refraction is 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 8 days prior to enrollment.

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

1a. If Yes, record the correction for the (right/left) study eye: _____ _____ @ _____ o
sph cyl axis

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

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

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

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

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** _____ ETDRSOS

To qualify as a study eye, visual acuity score must be ≥ 73 letters (approximately 20/32 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)

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

PRP Study

Enrollment 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.

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

H. BLOOD PRESSURE

1. Blood Pressure exam date: ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 8 days prior to enrollment)

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.

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

I. BASELINE OCT

1. OCT: Date Performed: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*
(Must be done within 8 days prior to enrollment)

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

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

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)

Note: Standard deviation should be <= 10% of the center point 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. Signal Strength ***(if OCT 3 Version 4 was used please enter signal strength)***: _____

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

7. Thickness of the central subfield on OCT: Right Eye (OD)/ Left Eye (OS)_____ microns

COMMENTS

PRP Study

Enrollment Form

J. FUNDUS PHOTOGRAPHY

7-Field fundus photos are required on the right/left study eye.

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

__ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Must be performed within 8 days prior to enrollment

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

1c. Camera Used: _____

COMMENTS

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

K. 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**

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

Eye being assessed for eligibility: _____

PRP Study

Enrollment Form

L. 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: ____ ____ ____ ____ ____

Scatter Laser Photocoagulation Treatment Form for the Right/Left Eye

Complete a treatment form for each PRP sitting

Will/did the study eye receive PRP at this visit? Yes No
If 'No,' reason: macular edema present and treatment deferred
other _____

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

Name of Investigator _____

Scatter Laser Photocoagulation Form for the right/left eye

1. **Eye Treated:** OD OS
2. **Treatment Regimen:** 1 PRP sitting 4 PRP sittings

1 PRP Sitting Regimen: 1 sitting with a minimum of 1200 to a maximum of 1600 burns
4 PRP Sittings Regimen: 4 sittings, with approximately 300 burns in each of the first two sittings and investigator judgment for the number of burns for the third and fourth sittings as long as the total for the four sittings is at least 1200 to 1600 burns

3. **Visit Technique Performed:** _____

Note: An indirect laser approach cannot be used.

4. **Size (on retina):** _____
5. **Lens Type:** Rodenstock Three mirror contact lens Other_____
6. **Average Power:** _____ **mW**
7. **Wave Length:** Green Yellow Red
8. **Number of Burns:** _____
9. **Was a retrobulbar injection performed?** Yes No

10a. Were post treatment posterior pole and 2 peripheral fields photos obtained after treatment? Yes No
(only required after the first sitting)

10b. If no, why not? _____

11a. Did the patient experience any complications as a result of the PRP? Yes No

11b. If yes describe:_____

12a. Did any portion of the procedure deviate from the protocol? Yes No

12b. If yes, explain: _____

COMMENTS

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

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

PRP 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*

1. **Did the patient experience any unanticipated adverse events in the study eye as a result of the PRP (not reported on a previous case report form)? Yes No (If Yes, please complete an Adverse Event form.)**

2. **Has the patient's study eye received any treatment for DME since the prior protocol visit (not reported on a previous case report form)? Yes No**

   If yes, describe: _____

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

   If yes, describe: _____

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.

PRP Study
Follow-Up Visit Form

B. VISUAL ACUITY SECTION

If visit is the 2 day or 4 week then refraction is not required at this visit. Test visual acuity of both eyes without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

If visit is the 17 week or 34 week then refraction is required at this visit in the study eye. If refraction is performed on the nonstudy eye it may be recorded. Test visual acuity of 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***

B1. REFRACTION

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)

If Yes, Refractionist: _____

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

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

PRP Study
Follow-Up Visit Form

B2. VISUAL ACUITY – Visual acuity measurement is required in both eyes at this visit.

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** _____

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

VA Tester: _____

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

B3. CLINICAL EXAM

1. Did visual acuity decrease by 10 or more letters in the study eye since baseline? Yes No

2. If Yes, will a refraction and repeat visual acuity test be performed? Yes No

If Yes, please complete the Repeat Visual Acuity Section

If No, select the cause for the visual acuity decrease:

☐ Macular edema

☐ Vitreous Hemorrhage

☐ Other _____

COMMENTS

PRP Study
Follow-Up Visit Form

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.

PRP Study
Follow-Up Visit Form

C. REPEAT VISUAL ACUITY SECTION (OPTIONAL)

Refraction and/or repeat visual acuity should be performed in the study eye if there has been a 10 or more letter visual acuity loss since baseline.

Was a refraction performed after the initial visual acuity testing in the study eye? Yes No

If Yes, enter refraction and refractionist below:

Refractionist: _____

Refraction: OD _____ _____ @ _____ o
sph cyl axis

Was visual acuity testing repeated in the study eye? No Yes

If Yes, enter below:

EVA Instrument # *(from label):* _____

ETDRS letter score: Study Eye: _____

VA Tester: _____

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

Please detail: _____

_____

CLINICAL EXAM

1. Did visual acuity decrease by 10 or more letters in the study eye since the previous visit after refraction and repeat visual acuity testing? Yes No

If Yes, select the cause for the visual acuity decrease:

☐ Macular edema

☐ Vitreous Hemorrhage

☐ Other _____

PRP 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.

PRP Study
Follow-Up Visit Form

D. OCT

Note: OCT will be performed on the study eye at each follow-up visit.

OCT measurement is required for the study eye.

OCT 3 or higher must be used.

Will OCT be performed on the study eye at this visit? Yes No

If No, reason: _____

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

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

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

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)

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

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

7. Thickness of the central subfield on OCT: Right Eye/ Left Eye _____ microns

COMMENTS

PRP Study
Follow-Up Visit Form

E. FUNDUS PHOTOGRAPHY

Note: Photos will be performed on the study eye at the 34-week follow-up visit only.

Will fundus photos be obtained on the study eye at this visit? Yes No

If No, reason: _____

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

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

1c. What photographs were completed? 3-fields are required for this visit.
Required fields
Other; explain _____

1d. Camera Used: _____

COMMENTS

PRP Study
Follow-Up Visit Form

F. IMPRESSION/PLAN

1. Will the study eye receive treatment for DME at this visit? Yes No

Note: Treatment for DME should be deferred until completion of the 17-week visit.

Mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Peribulbar Triamcinolone Acetonide**
- ☐ **Intravitreal Triamcinolone Acetonide**
- ☐ **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.

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

PRP Study
Adverse Event Form

Only adverse events that are possibly related to study procedures AND are unanticipated should be reported.

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

A. DESCRIPTION OF EVENT

1. Type of Event: ☐ Systemic ☐ Right Eye (OD) ☐ Left Eye (OS)
check one (if an event occurred in both eyes, complete and AE form for each eye)

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

6. Is there a reasonable possibility that the event was caused by the study treatment? Yes No

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

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

_____

_____

Other: Yes No
If yes, detail_____

PRP Study
Adverse Event Form

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

_____

_____

_____

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

If 'Yes', list: _____

_____

_____

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

If 'Yes', detail: _____

_____

_____

PRP Study
Adverse Event Form

6. Concomitant medical products and therapy dates (exclude treatment of event)? Yes No
If 'Yes', please explain: _____

_____

_____

COMMENTS

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.

Question # A.6

Relationship to Study Treatment

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)

PRP Study
Adverse Event Form

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.

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.

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.

PRP Study
Adverse Event Form

Question # D.5
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.*

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.