

DRUGS, INC.	GENERAL PHYSICAL EXAMINATION SCREENING																					
PROTOCOL NO. 1234-56	INVESTIGATOR NUMBER <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					SCREENING NUMBER <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					RANDOMIZATION NUMBER <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					PATIENT INITIALS <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 33%;"></td><td style="width: 33%;"></td><td style="width: 33%;"></td></tr><tr><td style="font-size: 8px; text-align: center;">first</td><td style="font-size: 8px; text-align: center;">middle</td><td style="font-size: 8px; text-align: center;">last</td></tr></table>				first	middle	last
first	middle	last																				

VITAL SIGNS																					
VITAL SIGNS DATE <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 33%;"></td><td style="width: 33%;"></td><td style="width: 33%;"></td></tr><tr><td style="font-size: 8px; text-align: center;">day</td><td style="font-size: 8px; text-align: center;">month</td><td style="font-size: 8px; text-align: center;">year</td></tr></table>				day	month	year	HEIGHT (in) <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					WEIGHT (lbs) <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					BODY MASS INDEX <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>				
day	month	year																			
BLOOD PRESSURE AFTER SITTING 3 MINUTES (mm Hg) (Systolic) (Diastolic) <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					HEART RATE AFTER SITTING 3 MINUTES (beats per minute) <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					RESPIRATION RATE (breaths per minute) <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>					BODY TEMPERATURE (°F) <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td><td style="width: 25%;"></td></tr></table>						

PHYSICAL EXAMINATION									
Physical Exam Date: <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 33%;"></td><td style="width: 33%;"></td><td style="width: 33%;"></td></tr><tr><td style="font-size: 8px; text-align: center;">day</td><td style="font-size: 8px; text-align: center;">month</td><td style="font-size: 8px; text-align: center;">year</td></tr></table>							day	month	year
day	month	year							

ND = Not Done N = Normal A = Abnormal (If any answer is abnormal, give pertinent details)

	ND	N	A	SPECIFY SIGNIFICANT ABNORMALITIES—PLEASE PRINT
Head, Eyes, Ears, Nose & Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Chest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Breasts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Back	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genitalia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Central Nervous System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
DRE, including Prostate Exam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other, specify:			<input type="checkbox"/>	
Other, specify:			<input type="checkbox"/>	

DRUGS INC.		PHASE II CLINICAL TRIAL OF DRUG ABC				For Company Use Only
STUDY NO. 123-45	INVEST. NO.	PATIENT NO.	PATIENT INIT.	INVESTIGATOR NAME		Monitor Review _____ Date _____

DEMOGRAPHICS				
SEX <input type="checkbox"/> M <input type="checkbox"/> F	DATE OF BIRTH ____/____/____ M D Y	WEIGHT (kg) ____ ____ ____.____	HEIGHT (cm) ____ ____ ____.____	RACE <input type="checkbox"/> WHITE (1) <input type="checkbox"/> BLACK (2) <input type="checkbox"/> ASIAN (3) <input type="checkbox"/> OTHER (4) _____

GENERAL MEDICAL HISTORY					
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DATE OF EXAMINATION ____/____/____ M D Y					
--	--	--	--	--	--

DOES THIS PATIENT HAVE A PAST HISTORY OF:	0 = NO 1 = YES		IF YES, CIRCLE STATUS AT START OF STUDY 1 = STABLE 2 = UNSTABLE 3 = UNKNOWN 4 = RESOLVED				DATE OF ONSET			DATE OF RESOLUTION		
	0	1	1	2	3	4	M	D	Y	M	D	Y
Malignancy	0	1	1	2	3	4						
Cardiovascular Disease	0	1	1	2	3	4						
Pulmonary Disease	0	1	1	2	3	4						
Gastrointestinal Disease	0	1	1	2	3	4						
Hepatobiliary Disease	0	1	1	2	3	4						
Genitourinary Disease	0	1	1	2	3	4						
Gynecological Disease	0	1	1	2	3	4						
Musculoskeletal Disease	0	1	1	2	3	4						
Metabolic Disease	0	1	1	2	3	4						
Psychiatric Disease	0	1	1	2	3	4						
Neurological Disease	0	1	1	2	3	4						
Allergies, including drugs	0	1	1	2	3	4						
Infectious Disease	0	1	1	2	3	4						
Skin Disease	0	1	1	2	3	4						
Organ Transplant	0	1	1	2	3	4						
Other (specify)	0	1	1	2	3	4						



**STUDY NO. 456-78
INTRAOCULAR LENS INVESTIGATION**

THE LENS CO. USE ONLY

PATIENT NO.

PATIENT INIT.

PRINCIPAL INVESTIGATOR

CM REVIEW _____

DATE _____

POSTOPERATIVE REPORT : FORM 1 - DAYS 1 THROUGH 6

EXAMINATION DATE

____/____/____
M D Y

PATIENT AVAILABILITY

- PATIENT UNAVAILABLE FOR THIS VISIT (1)
- OR**
- PATIENT DISCONTINUED : CHECK ONE
- DIED (2)
- MOVED (3)
- LENS REPLACED (4)
- LOST TO FOLLOW-UP - UNABLE TO LOCATE (5)
- OTHER _____ (6)

INTRAOCULAR LENS EVALUATION

- NONE (0)
- OR**
- CHECK ALL THAT APPLY:
- BENDING OR DISTORTION TO OPTIC (1)
- NO CAPSULAR FIXATION (2)
- NONPIGMENT PRECIPITATION (3)
- PIGMENT PRECIPITATION (4)
- TISSUE INGROWN TO OPTIC (5)
- OTHER _____ (6)

FELLOW EYE STATUS

CHECK ONE:

- NORMAL (1)
- CATARACT (2)
- MONOFOCAL IMPLANT (3)
- MULTIFOCAL IMPLANT (4)
- OTHER _____ (6)

LENS POSITION

- CENTERED (0.0 - 0.5 mm FROM CENTER) (1)
- MILDLY DECENTERED (0.5 - 1.0 mm FROM CENTER) (2)
- MODERATELY DECENTERED (1.0 - 2.0 mm FROM CENTER) (3)
- DISLOCATED (>2.0 mm FROM CENTER) (4)
- IF NOT CENTERED: DIRECTION OF LENS MOVEMENT
- _____ O'CLOCK

INTRAOCULAR PRESSURE

- APPLANATION (1)
- SCHIOTZ (2)
- AIR PUFF (3)
- _____mm

LENS MOVEMENT

- NONE (0)
- OR**
- CHECK ALL THAT APPLY:
- IN-PLANE ROTATION (1)
- TILTED (2)
- OTHER _____ (3)

ANTERIOR CHAMBER DEPTH ESTIMATE

- NORMAL (1)
- SHALLOW (2)

POSTERIOR CAPSULOTOMY PERFORMED SINCE LAST VISIT

- NONE (0)
- OR SPECIFY:**
- DATE ____/____/____
- ND: YAG LASER (1)
- SURGICAL (KNIFE, NEEDLE) (2)
- OTHER _____ (3)
- DAMAGE TO INTRAOCULAR LENS
- NONE (0)
- OR**
- SPECIFY _____ (1)

CORTICOSTEROIDS USED

- NONE (0)
- SYSTEMIC (1)
- TOPICAL (2)

ANTIBIOTICS USED

- NONE (0)
- SYSTEMIC (1)
- TOPICAL (2)

CONTINUE TO NEXT PAGE

PRINCIPAL INVESTIGATOR'S SIGNATURE

DATE



**STUDY NO. 456-78
INTRAOCULAR LENS INVESTIGATION**

THE LENS CO. USE ONLY

PATIENT NO.

PATIENT INIT.

PRINCIPAL INVESTIGATOR

CM REVIEW _____

DATE _____

POSTOPERATIVE REPORT : FORM 1 - DAYS 1 THROUGH 6 (CONTINUED)

PRE-EXISTING PATHOLOGY NOT EVIDENT PREOPERATIVELY

NONE (0)

OR

SPECIFY _____ (1)
(e.g. MACULAR DEGENERATION)

OTHER COMPLICATIONS

NONE (0)

OR

CHECK ALL THAT APPLY:

- HYPHEMA (1)
- WOUND LEAK (2)
- FLAT ANTERIOR CHAMBER (3)
- ANTERIOR SEGMENT NEOVASCULARIZATION (4)
- FISTULA BLEB (5)
- NON-CONSTRICT PUPIL (6)
- MACULAR EDEMA - CONFIRMED BY ANGIOGRAM (7)
- MACULAR EDEMA - UNCONFIRMED BY ANGIOGRAM (8)
- PUPILLARY BLOCK (9)
- SECONDARY GLAUCOMA (10)
- DETACHED DESCEMENT'S MEMBRANE (11)
- CORTICAL REMNANTS (12)
- NUCLEAR REMNANTS (13)
- CYCLITIC MEMBRANE (14)
- ANTERIOR CHAMBER VITREOUS HERNIA (15)
- VITREOUS TO WOUND (16)
- INTRAOCULAR FOREIGN BODY (17)
- VITRITIS (18)
- ENDOPHTHALMITIS (19)
- CHOROIDAL DETACHMENT (20)
- RETINAL DETACHMENT (21)
- RETINAL VASCULAR OCCLUSION (22)
- OPTIC ATROPHY (23)
- OTHER _____ (24)

ADVERSE REACTION

NONE (0)

OR

CHECK ALL THAT APPLY:

- HYPOPYON (1)
- INTRAOCULAR INFECTION (2)
- ACUTE CORNEAL DECOMPENSATION (3)
- SECONDARY SURGICAL INTERVENTION (4)

AN ADVERSE REACTION FORM **MUST** BE COMPLETED FOR ANY "YES" ANSWER.
THE LENS COMPANY MUST BE NOTIFIED WITHIN 5 DAYS OF ANY
ADVERSE REACTION NOT PREVIOUSLY REPORTED

ASSOCIATED DIAGNOSES

NONE (0)

OR

CHECK ALL THAT APPLY:

- FUCH'S DYSTROPHY/GUTTATA (1)
- MACULAR DEGENERATION (2)
- GLAUCOMA (NON-SURGERY RELATED) (3)
- DIABETIC RETINOPATHY/MACULOPATHY (4)
- POSTERIOR CAPSULE HAZE (5)
- ELSCHNING PEARLS (6)

IRITIS

NONE (NONE TO TRACE FLARE AND/OR CELLS) (0)

OR

CHECK ONE OF THE FOLLOWING:

- MILD (1-FLARE AND/OR CELLS) (1)
- MODERATE (2-FLARE AND/OR CELLS) (2)
- SEVERE (3-4 FLARE AND/OR CELLS) (3)

CORNEAL EDEMA

UPPER
 NONE (0)

OR

CHECK ONE OF THE FOLLOWING:

- MILD (1)
- MODERATE (2)
- FOLDS IN D'S (3)

LOWER
 NONE (0)

OR

CHECK ONE OF THE FOLLOWING:

- MILD (1)
- MODERATE (2)
- FOLDS IN D'S (3)

**THIS CONCLUDES FORM 1.
PLEASE MAIL TO THE LENS COMPANY
UPON COMPLETION.**

PRINCIPAL INVESTIGATOR'S SIGNATURE

DATE