OHTS Adverse Event: AE

- Complete Adverse Event form for patients in observation and medication group if patient:
  - Experiences ocular or systemic symptoms
  - Experiences a serious event, illness/accident
  - Is hospitalized
  - Checks "somewhat" or "a lot" on Symptom Checklist (SY)
  - Complete at your discretion if patient checks "a little" on Symptom Checklist (SY)
- **Complete an AE form <u>for each</u> Adverse Event symptom cluster**

Patient ID: SITE IDNUM NAMECODE

Today's Date: EXAMDATE
mm dd yy

1. Describe the adverse event: AETEXT (formerly AE TEXT1, AE TEXT2, AE TEXT3) _____

2. Diagnosis, if known: DIAGNOS _____

3. Date of onset: AEONSET
mm dd yy
Check here if estimated date: ☐

ESTONSET=M if month estimated or ☐
ESTONSET=D if day estimated

4. Severity: Check only one.

SEVERITY
- Patient not aware of condition
- Awareness of system cluster symptom-but easily tolerated
- Discomfort causing interference of usual activity
- Incapacitating with inability to work or do usual activity
- Patient death **(Complete "Confirmation of Death: DT" Form)**

5. Check organ system(s) affected by sign/symptom (cluster):

OCULAR	Ocular	CARDIO	Cardiovascular
CONSTIT	General constitutional symptoms	BLOOD	Blood & Immune system
SKINHAIR	Skin, Hair & Nails	GASTRO	Gastro-Intestinal
MUSCULO	Musculo-Skeletal	GENITO	Genito-Urinary
HEADNECK	Head & Neck	NEURO	Neurologic
ENDOCRIN	Endocrine	PSYCH	Psychiatric
RESPIR	Respiratory	BLOOD	Other SYSTEXT _____

6. Description: Check all that apply.

- MEDICAL Condition requiring medical attention
- SURG_EYE Ocular surgery
- SURG_OT Surgery excluding ocular surgery
- DISABIL Substantial or permanent disability
- OUPTHOSP Outpatient hospitalization (≤ 23 hour stay)
- INPTHOSP Inpatient hospitalization (>23 hour stay)
- LONGHOSP Prolongation of existing hospitalization
- LIFE Life threatening (patient in immediate risk of dying from event as it occurred)
- CANCER Cancer
- OVERDOSE Overdose
- OTDESCR Other DESCRIP _____
- NONEABOV None of the above

OHTS Adverse Event: AE

Patient ID: SITE IDNUM NAMECODE

Today's Date: EXAMDATE
mm dd yy

1. Outcome of event (Leave blank if patient is deceased): AEOUTCOM
   - ☐ No longer present/no residual effects
   - ☐ No longer present/residual effects
   - ☐ Ongoing
   - ☐ Undetermined

NOMEDS

2. If patient is not currently taking study medication, check here ☐; otherwise complete remainder of form.

	Drug #1	Drug #2	Drug #3
3. List drug name and %:	AEDRUG1	AEDRUG2	AEDRUG3
4. Relation to study drug(s):	AERELAT1	AERELAT2	AERELAT3
Not related	☐	☐	☐
Possibly related	☐	☐	☐
Probably related	☐	☐	☐
Definitely related	☐	☐	☐

5. Action being taken regarding study drug(s) **due to reported AE**:
   (Leave blank if patient is deceased)

	AEACTN1	AEACTN2	AEACTN3
No change	☐	☐	☐
Reduced	☐	☐	☐
Discontinued temporarily	☐	☐	☐
Discontinued permanently	☐	☐	☐

_____ PIDATE
Investigator Signature (required) Date

Form Completed By (PI or CC): AEBY