Complete Adverse Event form for adverse events occurring from consent date of OHTS Phase 3 to last visit in OHTS Phase 3.

1. Describe the adverse event: __________________________________________________________

2. Diagnosis, if known: ________________________________________________________________

3. Date of onset: mm/dd/yy Check here if estimated date: □

4. Severity: Check only one.
   □ 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): Check all that apply.
   □ Ocular
   □ General constitutional symptoms
   □ Skin, Hair & Nails
   □ Musculo-Skeletal
   □ Head & Neck
   □ Endocrine
   □ Respiratory
   □ Cardiovascular
   □ Blood & Immune system
   □ Gastro-Intestinal
   □ Genito-Urinary
   □ Neurologic
   □ Psychiatric
   □ Other ________________________________

6. Description: Check all that apply.
   □ Condition requiring medical attention
   □ Ocular surgery
   □ Surgery excluding ocular surgery
   □ Substantial or permanent disability
   □ Outpatient hospitalization (≤ 23 hour stay)
   □ Inpatient hospitalization (>23 hour stay)
   □ Prolongation of existing hospitalization
   □ Life threatening (patient in immediate risk of dying from event as it occurred)
   □ Cancer
   □ Overdose
   □ Other ________________________________
   □ None of the above
7. Outcome of event (Leave blank if patient is deceased): Check only one.
   - ☐ No longer present/no residual effects
   - ☐ No longer present/residual effects
   - ☐ Ongoing
   - ☐ Undetermined

8. Relation to Participation in OHTS Phase 3: Check only one.
   - ☐ Not related
   - ☐ Possibly related
   - ☐ Probably related
   - ☐ Definitely related

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Investigator Signature (required) ___________________________ Date __________

Form Completed by (CC or PI): __________