**Purpose:** This template may be used to record and track inclusion and exclusion of research participants.

**Responsibility:** To be used by Principal Investigators and study team members who are delegated to assess and record eligibility.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory text** are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified or deleted. Example text is indicated in [italics]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

**Inclusion/Exclusion Checklist Template**

**Participant/ID:**

**Protocol #:**

**Study Title:**

**Principal Investigator:**

**Protocol Version:**

**Inclusion Criteria (All answers must be YES to enter the study)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Criteria  | Assessment Instrument  | YES | NO | Source Date |
| 1. *[Age 12 – 18]*
 | *[General Interview]* | *Yes* |  | *6/11/2020* |
| 1. *[Medically stable (i.e.,…)]*
 | *[EMR, Treating Physician Notes, etc.]*  |  |  |  |
| 1. *[Reliable Transportation]*
 | *[Phone Screen]*  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| … |  |  |  |  |

**Exclusion Criteria (All answers must be NO to enter the study)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Criteria  | Assessment Instrument  | YES | NO | Source Date |
| *1. [History of FBT]* | *[General Interview]*  |  | *No* | *6/11/2020* |
| *2. [IBW <75]* | *[Vitals]*  |  |  |  |
| *3. [Substance Abuse]*  | *[KSADS]*  |  |  |  |
| *4. [Prohibited Medication]*  | *[Concomitant Medication Log]*  |  |  |  |
| *5.* |  |  |  |  |
| *6.* |  |  |  |  |
| *…* |  |  |  |  |

**Signature of PI Confirming Eligibility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Randomization Checklist Template**

**Participant/ID:**

**Protocol #:**

**Study Title:**

**Principal Investigator:**

**Protocol Version:**

**Pre-Screening Requirements**

|  |  |  |  |
| --- | --- | --- | --- |
| Criteria  | Required Timeframe | Notes | Source Date |
| 1. *[Pre-screen ICF]*
 | *[Prior to collection of archival tissue]* |  | *6/01/2020* |
| 1. *[Molecular testing results]*
 | *[Within 28 days of randomization]*  |  | *6/11/2020* |
| 3.  |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |
| 6. |  |  |  |
| … |  |  |  |

**Randomization Requirements**

|  |  |  |  |
| --- | --- | --- | --- |
| Criteria  | Required Timeframe | Notes | Source Date |
| *1. [Main study ICF]* | *[Prior to research assessments]*  |  | *6/11/2020* |
| *2. [Imaging assessments]* | *[Within 28 days of randomization]*  |  |  |
| *3. [Physical exam]*  | *[Within 21 days of randomization]*  |  |  |
| *4. [Ophthalmology exam]* | *[Within 14 days of randomization]*  |  |  |
| *5.* |  |  |  |
| *6.* |  |  |  |
| *…* |  |  |  |

**Signature of PI Confirming Eligibility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**