**RESEARCH SUBJECT ELIGIBILITY ASSESSMENT FORM**

|  |
| --- |
| CRRO Template Version 1.0, 4/25/2017    **GENERAL INSTRUCTIONS** – delete this box from the completed form  **NOTE: This form is designed to be a starting point on eligibility assessment. Update it as necessary for your specific study.**  All participants enrolled in the study must meet all inclusion criteria and not meet any of the exclusion criteria. All changes to inclusion/exclusion criteria must be approved by the IRB prior to implementation. Remember to modify this template any time the inclusion/exclusion criteria is changed.  **Participant records should include source documentation (lab results, medical records, questionnaires, data collection tools, etc.) to support that the participant meets eligibility criteria.**  All staff responsible for reviewing and/or determining subject eligibility should be listed on the IRB application, appropriately trained by study PI, and listed on the study delegation log.  Red text represents instructions to you – to be deleted from the final version. |

|  |  |
| --- | --- |
| **Study Name:** |  |
| **IRB Protocol #:** |  |
| **Protocol Version # and/or Date:** |  |
| **Principal Investigator:** |  |

[Complete this table with all inclusion/exclusion criteria listed in the IRB-approved protocol. Modify the number of rows as needed depending on the number of inclusion/exclusion criteria in your protocol.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SUBJECT # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | |
| **INCLUSION CRITERIA**  ***Must be "yes"*** | **Yes** | **No** | **Location of supporting source documentation** | **Notes** |
| **1.** | 🢭 | 🢭 |  |  |
| **2.** | 🢭 | 🢭 |  |  |
| **3.** | 🢭 | 🢭 |  |  |
| **4.** | 🢭 | 🢭 |  |  |
| **5.** | 🢭 | 🢭 |  |  |
| **EXCLUSION CRITERIA**  ***Must be "no"*** | **Yes** | **No** | **Location of supporting source documentation** | **Notes** |
| **1.** | 🢭 | 🢭 |  |  |
| **2.** | 🢭 | 🢭 |  |  |
| **3.** | 🢭 | 🢭 |  |  |
| **4.** | 🢭 | 🢭 |  |  |
| **5.** | 🢭 | 🢭 |  |  |

**This subject is:**  
  
 **Eligible** **for participation** **Ineligible for participation**

[Signed by study team member who is (1) qualified to assess eligibility and (2) delegated this study task by the PI]

|  |  |
| --- | --- |
| **Signature:** | **Date:** |
| **Printed Name:** |  |