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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.  **NOTE: This form is designed to be a starting point on the Eligibility Criteria Checklist. 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. * Notes on this document or kept elsewhere should include any discussion as to why changes or allowances were made for a specific participant including documentation of sponsor or IRB approval as applicable. * List all of the inclusion/exclusion criteria on the assessment tool. Add rows as needed to list each inclusion and exclusion criteria separately. * All inclusion and exclusion criteria should be added with one row per criterion. Criteria should not be combined or shortened in any way. They must be copied in full and completely from either the INSPIR application or protocol. * Not Applicable and a checkbox should be added as appropriate. If a Not Applicable is added, the “all should be yes” or “all should be no” must be updated to include that allowance.   + For example, if enrolling women and men, a not applicable checkbox should be available unless the study plans to complete a pregnancy test on all study candidates regardless of gender. * Supporting source documentation location should be included to provide evidence of the criteria being met.   + Examples of locations could include but are not limited to: clinical visit on a specific date or lab result in medical record, verbal self-report, questionnaire, survey, or source data collection form. * Delete the CRRO template version date and add in the study-specific version date of this document. * When amendments are made to the eligibility criteria and approved by the IRB, this document should be updated and the version date should be updated as well. |

| **Eligibility Criteria** | | | | | |
| --- | --- | --- | --- | --- | --- |
| *Inclusion Criteria (all should be yes)* | | | | Date Confirmed | Supporting Source Documentation Location |
| [Insert full criterion directly from IRB-approved protocol] | | Yes | No |  |  |
| [Insert full criterion directly from IRB-approved protocol] | | Yes | No |  |  |
| *Exclusion Criteria (all should be no)* | | | | Date Confirmed | Supporting Source Documentation Location |
| [Insert full criterion directly from IRB-approved protocol] | | Yes | No |  |  |
| [Insert full criterion directly from IRB-approved protocol] | | Yes | No |  |  |
| **Notes**  *No notes or notes documented elsewhere: specify where: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| **Individual Eligible for Participation** | Yes, eligible for participation. All inclusion criteria are *Yes* and all exclusion criteria are *No*.  No, not eligible for participation. One or more inclusion criteria are *No* or one or more exclusion criteria are *Yes*. | | | | |
| **Study team member *Completing Eligibility Assessment* and *Confirming Eligibility*** | *I have reviewed all inclusion and exclusion criteria and I confirm that this individual is eligible to participate in the study.*  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| *This must be signed by a study team member who is listed within the IRB INSPIR submission, is qualified to assess eligibility by training, licensure, or other documented qualification, has been delegated to perform this task by the Principal Investigator, and is documented on the Delegation of Authority log.* | | | | | |