

## ELIGIBILITY CHECKLIST INSTRUCTIONS

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### PURPOSE

This tool is intended to assist the user in documenting participant eligibility by providing a framework for the screening process with the potential study subject.

### HOW TO USE

- Customize the form to include the inclusion/exclusion criteria listed in your study protocol.
- When screening the participant, complete the form header by adding the Study title, Participant ID code, and Participant initials.
- The study team member screening the participant should complete the body of the form as follows:
  - Document whether inclusion criteria are met
  - Document whether exclusion criteria are met
  - Complete the additional notes section as needed
  - Identify participant eligibility
- The study PI should review the form, and sign and date as appropriate.

### GOOD PRACTICE RECOMMENDATIONS

- If using the checklist, it should be printed and completed as a source document at the time of eligibility determination.
- Utilize the Additional Notes section of the form for clarification and or documentation of any special circumstances at the time of eligibility determination.
- Be sure to customize the template to make it study specific.