



Eligibility Checklist

Principal Investigator:	Study Title:
Subject Initials:	Subject ID:

GENERAL INSTRUCTIONS – Delete red text from the completed form. This document, along with all supporting documentation, should be retained in the participant’s research file.

Include all inclusion and exclusion criteria directly from the IRB approved study protocol. Additional rows should be added if needed.

If a protocol amendment changes inclusion/exclusion criteria, update form as applicable, including updating the version date in the footer. All changes to inclusion/exclusion criteria must be approved by the IRB prior to implementation.

Participant records should include source documentation (lab results, medical records, questionnaires, data collection tools, etc.) to support that the participant meets eligibility criteria.

All participants enrolled in the study must meet all inclusion criteria and not meet any exclusion 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.

Study eligibility must be verified by the PI prior to a participant’s enrollment.

Inclusion Criteria Must be ‘yes’	Yes	No	Comments (if applicable)



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Exclusion Criteria Must be 'no'	Yes	No	Comments (if applicable)

Eligibility Checklist Completed by:

Signature of Research Staff Member

Date

Printed Name of Research Staff Member

If any answers to inclusion criteria are 'no' or exclusion criteria 'yes', then the participant is not eligible to be enrolled.

The subject is: ☐ eligible / ☐ ineligible for participation in the above named study based on the inclusion/exclusion criteria as verified by a qualified investigator.

Verified by:



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Signature of Investigator

Date

Printed Name of Investigator