

# USA HEALTH

## 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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<b>Exclusion Criteria Must be 'no'</b>	<b>Yes</b>	<b>No</b>	<b>Comments (if applicable)</b>

**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**