



HEALTH CARE

HUMAN RESEARCH PROTECTIONS PROGRAM



Subject Eligibility Confirmation Checklist

➤ The purpose of this form is to verify subject eligibility throughout the screening process and before enrollment.

I. Study Information

Study Title:	
IRB Study #:	
Principal Investigator:	

II. Subject Information:

Subject Name/ID:	
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	

III. Inclusion/Exclusion Criteria

Inclusion Criteria (From IRB approved protocol)	Yes	No	Supporting Documentation	Initial* and Date
1.	<input type="checkbox"/>	<input type="checkbox"/>		
2.	<input type="checkbox"/>	<input type="checkbox"/>		
3.	<input type="checkbox"/>	<input type="checkbox"/>		
4.	<input type="checkbox"/>	<input type="checkbox"/>		
5.	<input type="checkbox"/>	<input type="checkbox"/>		
6.	<input type="checkbox"/>	<input type="checkbox"/>		
7.	<input type="checkbox"/>	<input type="checkbox"/>		
8.	<input type="checkbox"/>	<input type="checkbox"/>		
9.	<input type="checkbox"/>	<input type="checkbox"/>		
10.	<input type="checkbox"/>	<input type="checkbox"/>		
Exclusion Criteria (From IRB approved protocol)	Yes	No	Supporting Documentation	Initial* and Date
1.	<input type="checkbox"/>	<input type="checkbox"/>		
2.	<input type="checkbox"/>	<input type="checkbox"/>		
3.	<input type="checkbox"/>	<input type="checkbox"/>		
4.	<input type="checkbox"/>	<input type="checkbox"/>		
5.	<input type="checkbox"/>	<input type="checkbox"/>		
6.	<input type="checkbox"/>	<input type="checkbox"/>		
7.	<input type="checkbox"/>	<input type="checkbox"/>		
8.	<input type="checkbox"/>	<input type="checkbox"/>		
9.	<input type="checkbox"/>	<input type="checkbox"/>		
10.	<input type="checkbox"/>	<input type="checkbox"/>		



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*All subject files must include supporting documentation to confirm subject eligibility. The method of confirmation can include, but is not limited to, laboratory test results, radiology test results, subject self-report, and medical record review.

IV. Statement of Eligibility

This subject is **eligible** / **ineligible** for participation in the study based on the inclusion/exclusion criteria described in the IRB submission, as approved by the IRB.

Printed name of person assessing eligibility* :	
Printed name of person completing this form:	
Signature**:	Date***:

Investigator**:	Date***:
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- * Each criterion should be initial and dated by the designated research team member assessing the
- ** This form should be signed by the investigator to affirm subject is eligible for enrollment.
- *** Documentation of eligibility determination should be completed prior to enrollment into the study.