

Eligibility and Enrollment Log – Individual Participants

Audience: Clinical trial staff

All individuals enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application and approved by the IRB/REC.

A. Study Information

Protocol Number:	
Protocol Title:	
Principal Investigator:	

B. Participant Information:

Participant Name/Pre-Screening ID:	
Age: <input type="checkbox"/> >=18 - <65 years <input type="checkbox"/> >=65 - <74 years <input type="checkbox"/> >=75 - <84 years <input type="checkbox"/> >=85 years	
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown or undifferentiated	
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Trans-Male <input type="checkbox"/> Trans-Female <input type="checkbox"/> Gender nonconforming or unknown	
Ethnicity ¹ : <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino	
Race ¹ : <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other	

C. Inclusion/Exclusion Criteria

Inclusion Criteria (From IRB approved protocol)	Yes	No	Supporting Documentation ²
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"/>	

¹ Ethnicity and race categories listed here may need to be adapted to reflect specific geographic location and populations of interest.

² All participant files must include supporting documentation to confirm eligibility. Methods of confirmation can include, but is not limited to, documented vitals, laboratory test results, radiology test results, subject self-report, and medical record review.

Exclusion Criteria (From IRB approved protocol)			
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"/>	

D. Enrollment Tracking

Enrolled?		If no, why? Provide supporting Documentation ³
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	

E. Statement of Eligibility⁴

This individual is [eligible / ineligible] for participation in the study.

Signature:	Date:
Printed Name:	

³ All participant files must include supporting documentation to confirm eligibility. Methods of confirmation can include, but are not limited to, documented vitals, laboratory test results, radiology test results, subject self-report, and medical record review.

⁴ The designated Principal Investigator may be required to determine eligibility for research studies involving medical/clinical care.