

Retinal Microanatomy in Retinopathy of Prematurity (BabySTEPS2)

NCT04995341

Status	RECRUITING
Phase	Not Applicable
Sponsor	Duke University
Enrollment	236 participants

Key Eligibility Criteria

Inclusion (9)

- Children previously enrolled in BabySTEPS1 (Pro00069721) that have already consented to being contacted for this school age follow on study, Cohort 1 only
- Parent/Legal Guardian is able and willing to consent to study participation with follow up approximately between 4.5 and 5 years of age (consent available in Spanish* and English) (SA 1 only)
- Parent/Legal Guardian is able and willing to consent to study participation for the infant (SA 2 and 2c only)
- Infant/child undergoing clinically-indicated examination under anesthesia that may or may not have eye pathology (SA 2 only)
- Infant inborn or outborn at (SA 2 only):

... and 4 more (see full listing online)

Exclusion (3)

- Participant or Parent/Legal Guardian unwilling or unable to provide consent
- Adult participant or infant/child has a health or eye condition that preclude eye examination or retinal imaging (e.g. corneal opacity such as with Peter's anomaly or cataract) (SA2 only)
- Infant has a health condition, other than prematurity, that has a profound impact on brain development (e.g. anencephaly) (SA2 only)

Locations (2 total)

Duke University Eye Center, Durham, North Carolina, United States

University of Pennsylvania, Center for Preventive Ophthalmology and Biostatistics, Philadelphia, Pennsylvania, United States

<https://clinicaltrials.gov/study/NCT04995341>

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