

IDeA States Pediatric Clinical Trials Network

ECHO ISPCTN Junior Pilot Overview: Budget

August 22, 2022

Making a capitated budget

- Assign a cost to everything in your schedule of activities
 - Labs?
 - Procedures?
 - Equipment or medication?
 - Coordinator time per visit?
 - Consider data entry time
 - Time to enroll?
- Participant incentives
- How much PI oversight is needed?
- Site start up / close out?

Costs associated with these surveys?

Evaluation / Procedure	Screening / Consent	Delivery Hospital Stay	1 Month*	2 Months*	3 Months*	4 Months*	5 Months*	6 Months*	7 Months*	8 Months*	9 Months*	10 Months*	11 Months*	12 Months**
Baseline Cannabinoid Use Survey	х													
Follow Up Cannabinoid Use Survey								х						x
Perceived Stress Scale		х												х
Infant Temperament Survey					х									х
LENA Device Training		х												
LENA Device Recording			х	х	х	х	х	х	х	х	х	х	х	х
INTACT Intervention Coaching Session			x	x	x	x	x	х	х	x	x	x	x	x
Satisfaction Survey														х

^{*+/- 7} days of infant age

^{**}up to 14 months of infant age

Delivery Evaluation / Screening / 10 1 2 5 7 9 11 12 Hospital Procedure Consent Month* |Months* |Mont Stay Baseline Cannabinoid Х Use Survey Follow Up Cannabinoid Х Х Use Survey Perceived Х Х Stress Scale Infant Temperament Х Х Survey LENA Device Х Training LENA Device X Х Х Х Х Х Х Х Х Х Х Х Recording INTACT Intervention Х Χ Х Х Х Х Х Х Х Х Х Coaching Session Satisfaction Х Survey

How many LENAs do we need to buy? What do we need for training?

^{*+/- 7} days of infant age

^{**}up to 14 months of infant age

Evaluation / Procedure	Screening / Consent	Delivery Hospital Stay	1 Month*	2 Months*	3 Months*	4 Months*	5 Months*	6 Months*	7 Months*	8 Months*	9 Months*	10 Months*	11 Months*	12 Months**
Baseline Cannabinoid Use Survey	х	(
Follow Up Cannabinoid Use Survey								х						х
Perceived Stress Scale		х												х
Infant Temperament Survey					х									х
LENA Device Training		х												
LENA Device Recording			х	х	х	х	х	х	х	х	х	х	х	х
INTACT Intervention Coaching Session			х	х	х	х	х	х	х	х	х	х	х	х
Satisfaction Survey														х

Who is doing this? How much time?

^{*+/- 7} days of infant age

^{**}up to 14 months of infant age

Participant incentives at every touchpoint = 13 points of contact

Evaluation / Procedure	Screening / Consent	Delivery Hospital Stay	1 Month*	2 Months*	3 Months*	4 Months*	5 Months*	6 Months*	7 Months*	8 Months*	9 Months*	10 Months*	11 Months*	12 Months**
Baseline Cannabinoid Use Survey	х													
Follow Up Cannabinoid Use Survey								х						х
Perceived Stress Scale		х												х
Infant Temperament Survey					х									х
LENA Device Training		х												
LENA Device Recording			х	х	х	х	х	х	х	х	х	х	х	х
INTACT Intervention Coaching Session			x	x	х	х	х	х	х	х	х	x	х	х
Satisfaction Survey														х

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Translating PI time to capitation

- Assume salary cap
- \$203,700 for one year
 - -2.5% FTE
 - 52 weeks X 40 hours/week = 2,080 hours
 - 52 hours per year
 - -\$5,093
 - Assume equal enrollment across sites = \$5,093 should get you 7 participants
 - \$728 per participant

Framework

- 20 participants
- 3 sites

- \$67,060 in capitation fees
- \$60,000 in start up / close out (\$20k per site)
- \$61,110 Protocol chair support (30% FTE across 3 people)
- Total: \$189,280

	Cost	#events	Total	Assumptions
Per participant:			\$3,353	
Incentives	\$10	13	\$130	
LENA	\$100	1.25	\$125	Assume we'll need to replace 25%
Survey fees	\$10	2	\$20	Assuming fee for survey
Coach time	\$100	13	\$1300	Assumes individual sessions
Coordinator: enroll	\$300	1	\$300	2 hours per successful enrollment; assuming multiple failed approaches per success
Coordinator: per survey visit	\$130	3	\$390	2 hours
Coordinator: coach visits	\$30	12	\$360	0.5 hour to schedule, data entry
PI time	\$728	1	\$728	Assuming study finishes in 1 year

Formating