

TEDDY Protocol

Table 2. Follow-up Schedule

Sampling Frequency	Screening		Age in Months														Follow-Up									
	Birth	<4	2		3	4	5	6	7	8	9	10	11	12	15	18	21	24	27	12-48 mo Monthly Test	24-48 mo Every 3 mo Tests	24-48 mo Every 6 mo Tests	>48 mo Every 3 mo Tests	>48 mo Every 6 mo Tests	>48 mo Annual Tests	
			Inform Parents of child's HLA risk	Mail initial enrollment and questionnaire packet																						
Blood**	X*	X*			X+			X+			X+	X+	X+	X+	X+	X+	X+	X+	X+		X+#			X+#		
Stool					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				X (until 10 years)	X (at 10 years); Collection stopped August 2018	
Tap Water										X											Collected every 2 years beginning at the 36 month visit					
Toenail Clippings																		X			Collected every 2 years beginning at the 24 month visit; Starting May 2017 collected every 1 year					
Salivary Cortisol																					Collected when child is 3.5, 4.5 and 5.5 years of age					
Nasal Swab										X			X	X	X	X	X	X	X			X#			X#	
Urine																						X (begins at 3 years)		X		
Primary Tooth	Collect when tooth naturally falls out - ages will vary																									
Weight and Length/Height Measurements; Body composition on some subjects					X			X			X			X	X	X	X	X	X	X				X#		X#
Diet Questionnaires																										
-maternal pregnancy diet					X																					
-3 day diet record					X			X			X			X	X		X						X		X^	
Environmental Exposure Questionnaires																										
-maternal pregnancy/birth questionnaire					X																					
- parent questionnaire					X			X							X				X						Annually after 27 mos	
- child questionnaire																									X (begins at 10 years)	
Demographic/Family History/Other questionnaire										X											Demographic data will be updated every 2 years thereafter; Family History data will be updated every 4 years thereafter					
TEDDY Book Extraction					X			X			X			X	X	X	X	X	X	X				X#		X#
Child Behavior Checklist/Strengths and Difficulties Questionnaire																									CBCL completed when child is 3.5, 4.5 and 5.5 years of age; SDQ completed by both parent and child when child is 11.5 and 13.5 years of age	
Physical Activity Assessment																										X (begins at 5 years)%
Pubertal Status Assessment																									X (begins at 8 years)	

*If cord blood is not available at birth for HLA typing then capillary blood should be drawn.

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+ If venous blood is not available at every three month office visit, then capillary blood should be taken.

** A blood sample will be obtained by the 24 month visit from mothers who have type 1 or 2 diabetes or gestational diabetes as well as from a mother whose child is shown to be autoantibody positive at three or six months of age. An optional venous blood draw of the mother is obtained at 12-14 weeks of pregnancy, and at the birth of the baby.

#Children four years of age and older who have been deemed persistent autoantibody positive will remain on the three month visit schedule; this sample/form will be collected/completed at these visits.

^ Continue to collect 3 day diet records every 6 months from subjects who are single or multiple persistent confirmed autoantibody positive (even if the subject reverts to autoantibody negativity), stop 3 day diet record collections on all other subjects after the 10 year visit. Should a subject be deemed single or multiple persistent confirmed autoantibody positive after the 10 year visit, the 3 day diet record collection will be restarted at the next visit.

% Continue to collect physical activity assessments annually from subjects who are single or multiple persistent confirmed autoantibody positive (even if the subject reverts to autoantibody negativity), stop physical activity assessments on all other subjects after the 10 year visit. Should a subject be deemed single or multiple persistent confirmed autoantibody positive after the 10 year visit, the physical activity assessment will be restarted at the next visit.