

## TOHP Phase II Data Collection Schedule

	Screening &			----- Months of Follow-up -----																							
	Randomization			6			12			18			24			30			36			42			48		
Data	S V 1	S V 2	S V 3	F 1 1	F 1 2	F 1 3	F 2 1	F 2 2	F 2 3	F 3 1	F 3 2	F 3 3	F 4 1	F 4 2	F 4 3	F 5 1	F 5 2	F 5 3	F 6 1	F 6 2	F 6 3	F 7 1	F 7 2	F 7 3	F 8 1	F 8 2	F 8 3
BPA & Weight	A	A	A	A	S	S	A	S	S	A	A	A	A	S	S	A	S	S	A	A	A	B	S	S	C	S	S
Elig & Rand Form			A																								
Med HX & Demo		A																									
Medical History				A	S	S	A	S	S	A	A	A	A	S	S	A	S	S	A	A	A	B	S	S	C	S	S
Medication Use		A		A	S	S	A	S	S	A	A	A	A	S	S	A	S	S	A	A	A	B	S	S	C	S	S
Physical Activity			A								A									A							
Laboratory		A1	A2	sam++							A2									A2			B			C	
24-Hr Recall/ 3-Day			sam	sam+							sam									sam							
Anthropometrics			A							A										A							
Intervention Attendance*																											
Follow-up Status Updates**																											
Participant Evaluation																											

100 % of study population      70% of study population      33% of study population

- A = All Cases
- S = Safety Monitoring Only
- B = All except those terminating study at 36 mos
- C = All except those terminating at 36 or 42 months
  
- A1 = All cases – serum/local lab: glucose, creatinine, cholesterol
- A2 = All cases – 24 hour urine/central lab: sodium potassium, creatinine
  
- sam = sample of 900 to complete 24 Hour Recall and sample of 160 to complete 3 Day Food Records
- sam+ = sample of 160 to complete 3 Day Food Records only
- sam++ = 25% sample from all randomization groups to get urines at 6-months. In addition, 219 cases to get split samples to compare with 24 hour urine collections.
- \* = Form submitted periodically after randomization whether or not sessions were attended (every 60 days for 1<sup>st</sup> 6-months, after that every 90 days).
- \*\* = prn, to document participant needing special attention or follow-up for data collection
- + = Intervention specific participant evaluation forms were collected at the final termination visit (36, 42 or 48 months).