

The Food Biomarkers Study (FBS) – Phase 1

Study at a Glance

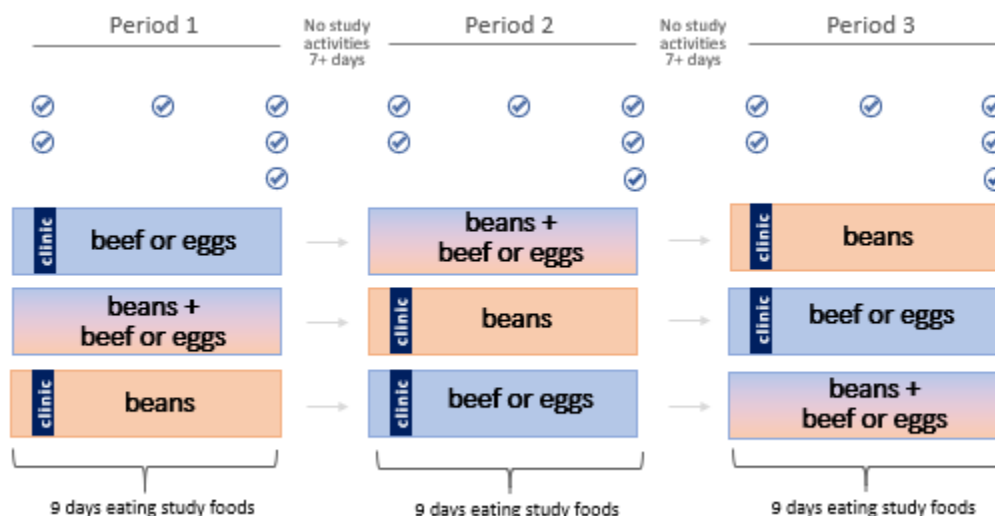
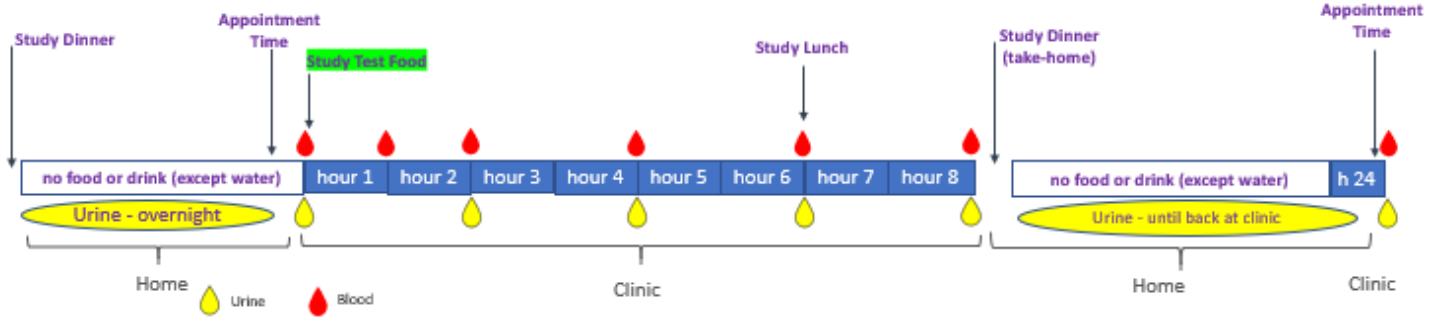


Table of study procedures							
Timeframe	Screening		Menu Period*				
Visit Name	Orientation	Eligibility Confirmation	Visit 1 (Day 1)	Visit 2 (Day 3)	Visit 2 Follow-up (Day 4)	Visit 3 (Day 6)	Visit 4 (Day 10)
Total number of each visit type	1 visit	1 visit	3 visits	3 visits	2 visits	3 visits	3 visits
Location	FH	FH & home	FH & home	FH & home	FH & home	FH & home	FH & home
Length of Visit	1.5 hours	30 minutes	< 30 mins	Up to 9 hours	30 minutes	30 minutes	30 minutes
Sign consent	•						
Height	•						
Weight	•		•	•		•	•
Blood Pressure	•						
Health Questionnaire	•						
3-day Food Record		•					
Diet order assignment		•					
Fasting blood draw		•		•	•	•	•
In-clinic postprandial test day **				•			
Overnight urine collection				•	•		
24-hour urine collection		•					•
Stool sample		•					•
Pick-up/return study meals			•	•	•	•	•
Daily study meal checklists				•	•	•	•
Wash-out (Periods 1 & 2 only)							•

*Participants will complete 3 menu periods. Each menu period has 4 study visits. 2 menu periods have a day-long postprandial test. Between each menu period, there is a 'wash-out' period where you return to your usual diet for at least one week.

** The post-prandial test involves a series of blood and urine collections after eating a test portion of a study food. This day-long procedure occurs in the clinic at Fred Hutch on Day 3 for 2 of the menu periods (Example schedule on next page.)

Post-prandial Test



Example – Post-prandial test day schedule:

In Clinic:

8:00am Bring overnight urine collection
Collect urine sample
Fasting blood draw
Catheter placed in arm

Begin post-prandial test

8:30am Begin eating study test food
8:50am End eating study test food
9:30am Collect blood sample
10:30am Collect blood & urine samples
12:30pm Collect blood & urine samples
2:30pm Collect blood & urine samples
Eat study lunch
4:30pm Collect blood & urine samples
Catheter removed
5:00pm Leave clinic

At home:

5:00 – overnight Collect all urine
8:00 pm Eat study dinner
9:00 pm Start fast

At clinic (next day):

8:00am Bring overnight urine collection
Collect urine sample
Fasting blood draw