## *Note:* please complete the Medication Form along with this form

1. \*\*Date and time of specimen collection:
2. \*\*What time elapsed between collection and processing?
3. \*\*What temperature was the sample stored at prior to processing?
4. \*\*Were there any modifications made (by the subject, their physicians, or the researchers) to the subject’s BASELINE medications right before the study commenced?

[ ]  Yes [ ]  No (STOP) [ ]  Unknown (STOP)

If the answer to #4 is YES, for EACH medication or mediation class modified, please note the following:

* 1. Name of the medication or class of medication:
	2. What changes were made to the medication (indicate initial vs. adjusted dose and frequency, if applicable)?

[ ]  Medication stopped

[ ]  Dose increased

[ ]  Dose decreased

[ ]  Frequency increased

[ ]  Frequency decreased

[ ]  Other, specify (e.g., route of administration changed):

Initial dose:

Initial frequency:

Adjusted dose:

Adjusted frequency:

* 1. When did changes occur relative to when a test, treatment, or other intervention was performed? (e.g., 24 hours before blood draw, 4 weeks prior to treatment, etc.)
1. What type of specimen was collected from the subject/participant?

[ ]  Blood, specify type: *(Choose one)*

[ ]  Whole blood

[ ]  Isolated peripheral blood mononuclear cells (PBMCs)

[ ]  Platelet-rich plasma

[ ]  Platelet-free plasma

[ ]  Serum

Indicate if subject/participant was fasting when blood was collected [ ]  Yes [ ]  No

Indicate collected volume (ml):

Indicate volume of collection tube (ml):

Indicate collecting system used [ ] Vacutainer [ ]  Needle

Specify collection tube: *(Choose one)*

[ ]  Polypropylene

[ ]  Polystyrene

[ ]  Other, specify:

Specify additives in collection tube: (*Choose one*)

[ ]  EDTA

[ ]  Citrate

[ ]  Heparin

[ ]  Lysing/stabilizing media, indicate additive and concentration/volume:

[ ]  None

Indicate brand name, catalog number:

Indicate if tubes are sterile: [ ]  Yes [ ]  No

Indicate if tubes are Endotoxin-free: [ ]  Yes [ ]  No

\*\*For serum/plasma, indicate timeframe and storage temperature between collection of blood and separation:

For PBMCs: specify method of isolation:

1. Ficoll: indicate brand name, catalog number and volume ratio used
2. CPT tube
3. Other, specify:

Indicate timeframe and storage temperature between blood collection and isolation of PBMCs:

[ ]  CSF, complete the following:

Opening pressure:

Amount of mL taken:

Speed and duration of centrifugation: (in G force or speed and name centrifugation):

WBC Cell count (include units):

RBC Cell count (include units):

Total Protein (include units):

Glucose (include units):

Method of testing for hemoglobin contaminants:

Specify collection tube: *(Choose one)*

[ ]  Polypropylene

[ ]  Polystyrene

[ ]  Other, specify:

[ ]  Urine

Indicate collected volume (ml):

Indicate if collected sample was first morning stream [ ]  Yes [ ]  No

[ ]  Saliva

Indicate collected volume (ml):

Indicate if stimulation was used:

[ ]  Yes, please describe:

[ ]  No (STOP)

Indicate if oral hygiene was used before collection:

[ ]  Yes, please describe:

Indicate time of oral hygiene procedure before collection:

[ ]  No (STOP)

[ ]  Other, specify:

For each specimen collected indicate:

1. Number of aliquots:
2. Volume per aliquot (if applicable, number of cells per aliquot):
3. Type of vial used:

Indicate brand name:

Catalog number:

Indicate if tubes are sterile: [ ]  Yes [ ]  No

Indicate if tubes are Endotoxin-free: [ ]  Yes [ ]  No

1. Final storage temperature:

### General Instructions

This form contains data elements that are collected for biomarkers. This form is to be used for each type of specimen collected. Most data elements on this CRF are classified as Supplemental (should only be collected if the research team considers them appropriate for their study). The remaining elements are classified as indicated by asterisks below:

\*\*Elements are classified as Supplemental – Highly Recommended

### Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* **Date/Time** – Record the date/time per the ISO 8601, the International Standard for the representation of dates and times (<http://www.iso.org/iso/home.html>). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
* **Did the subject/participant have any specimen(s) collected for biomarkers?** – If there was no specimen collected for biomarkers or it is unknown that a specimen was collected for biomarkers, discontinue obtaining information from subject/participant.
* **What type of specimen was collected from the subject/participant?** – Choose only one specimen type per CRF. If more than one specimen type collected, additional form(s) should be completed.
* **Were there any modifications made (by the subject, their physicians, or the researchers) to the subject’s BASELINE medications right before the study commenced?** If there were no medication changes made just prior to specimen collection, or if it is unknown if there were medication changes, discontinue obtaining information from subject/participant. “BASELINE” refers to medications the subject usually takes. Medications taken as needed (“PRN”) are considered “BASELINE” if the subject takes them reasonably regularly, i.e., once a week or more frequently.