The term, “specimen,” applies to blood, other bodily fluids, excreta, and tissues. When more than one type will be collected, clarify which type is being addressed for a specific item. When applicable, upload material transfer agreements and other supporting documentation.

1. What types of specimens will be collected for this research? Check all that apply.

Blood and blood fractions: plasma, serum, buffy coat, red blood cells

Bodily products: teeth, hair, nail clippings

Bodily fluids or excreta: sweat, urine, feces

Saliva and buccal cell

Sub-cellular components such as DNA or RNA

Cells or tissues from any part of the body

Other, specify:

1. Are you drawing blood?

Yes, answer the following questions.

No, go to the next question.

Will participants be healthy, nonpregnant adults who weigh at least 110 pounds/ 49.9 kg and will the amount drawn be no more than 550 ml in 8 weeks and collected no more often than twice per week?

Yes  No

If participants will be unhealthy or pregnant adults, or children, will the amount drawn be less than 50 ml or 3 ml per kg in 8 weeks and will collection occur no more often than twice per week?

Yes  No

1. Will specimen samples contain Personally Identifiable Information (PII)??

Yes  No

1. How will specimens be obtained? Check all that apply:

Blood, by finger, ear, or heel stick

Blood, by venipuncture

Biopsy

From samples obtained for diagnostic or therapeutic procedures

Hair or nail clippings in non-disfiguring manner

Deciduous teeth at time of exfoliation or during required extraction

Permanent teeth during required extraction

Sweat or other excreta or external secretions

Uncannulated saliva

Placenta removed at delivery

Amniotic fluid obtained when membrane ruptures before or during labor

Supra-/sub-gingival dental plaque and calculus collected during standard prophylactic scaling of teeth

Mucosal or skin cells collected by buccal or skin scraping or swab, or mouth washings

Sputum collected after saline mist nebulization

Existing samples (e.g. tissues from clinical care/surgery), specify source and IRBNet # if applicable:

Other, specify:

1. How much of each specimen will be obtained with each collection (in ml for liquids and mg for tissue)?
2. How many times and how frequently will specimens be collected?
3. What are the expected total number of specimen collections for each participant?        
   Specify where specimens be obtained, analyzed, and/or stored (include whether off-site facilities will be used, or whether tissue repository will be used):

1. Will you transfer specimens between WCM and a storage site?

Yes, specify the transporting standards below.

No, go to question 10.

What standards/requirements will be used for transporting the samples?

N/A, specimens will not be transported

WCM institutional biosafety committee requirements

External biosafety committee requirements, specify:

Collection and transport kits supplied by central lab that meets IATA requirements

Other, specify:

Will transferred specimens include identifiers?

Yes  No

1. Will specimens be stored for future use?

Yes, describe future uses:

No

1. Will specimens be sold?

Yes

No

1. How will specimens be disposed?

N/A, blood/specimens will be banked indefinitely for use by the PI

N/A, blood/specimens will be placed in a repository

Specimens will be disposed, describe process:

1. Does this research involve genetic (DNA) testing of specimens?

Yes, answer the rest of these questions.

No, do not answer the rest of these questions.

Will participants/tissue donors be informed of the results of the genetic testing?

Yes  No

Might results of genetic testing have implications for biological family members?

Yes  No

Will family members be informed of the results of the genetic testing when results may affect them?

Yes  No