

Note to File – Description of Prenatal Biological and Environmental Sample Collection

Pregnancy Visit 1 description (excerpted from Visit Information Sheet)

1. *During this visit, we would like to ask you some questions._*
 - This part of the visit will take about 30 minutes to complete. We will ask you some questions about yourself, your health and pregnancy, your lifestyle, and where you live. We will also ask you to complete some questions on your own about yourself and your experience with the Study. This should take about 10 minutes.
 - You can decide what questions you want to answer. If you feel uncomfortable about any question, you can skip it.
2. *During the time before and during pregnancy, we will ask for your permission to collect blood and urine samples from you twice. If you have already completed one Study visit that included sample collection, we would like to collect the second set of samples from you today. If this is your first Study visit, we would like to collect the first set of samples.*

Before this visit, we may have asked you not to eat or drink for 8 hours. Some of the tests we may do work best if you have not had anything to eat or drink for 8 hours._

- If you ate or drank anything in the past 8 hours, please let us know.
- This next part of the visit should take about 20 minutes.

We will ask you to:

- Collect some of your urine (about 2 ½ ounces) in a cup we provide.
 - We may test your urine for chemicals that may be present in the environment.

We also would like to:

- Collect a small amount (about 3 tablespoons) of your blood by using a small needle.
 - We may test your blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment.
3. *We may collect environmental samples from your home, or we may provide you with kits so you can collect the samples yourself. This part of the visit will take about 30 minutes.*
 - The environmental samples that will be collected are water samples from your faucet and dust from your vacuum cleaner. We may also collect dust from your household using a vacuum cleaner we provide.
 - We may test these samples for metals and other chemicals that may be present in the environment.
 - If you are asked to collect the environmental samples yourself, we will give you special kits to collect water and dust samples.
 - We will ask that you collect the samples at your earliest convenience. After you have collected these samples, please send the questionnaires back to us in the pre-paid envelopes and ship the samples back to the laboratory in the prepaid shippers that we provide.

Number of Participants: 1,533

Duration: 1.0 – 1.5 hours (for the entire visit)

Other burden associated with sample collection SAQs (after the visit): 30 minutes

Pregnancy Visit 2 description (excerpted from Visit Information Sheet)

1. *During this visit, we would like to ask you some questions._*

- This interview will take about 20 minutes to complete. We will ask you some questions about yourself, your health and pregnancy, your feelings and attitudes, and where you live. We will also ask you to complete some questions on your own about your experience with the Study. This should take about 5 minutes.
- You can decide what questions you want to answer. If you feel uncomfortable about any question, you can skip it.

2. *During the time before and during pregnancy, we will ask for your permission to collect blood and urine samples from you twice. If you have already completed one Study visit that included sample collection, we would like to collect a second set of samples from you today. If this is your third study visit, then we will not be collecting any biological samples.*

Before this visit, we may have asked you not to eat or drink for 8 hours. Some of the tests we may do work best if you have not had anything to eat or drink for 8 hours._

- If you ate or drank anything in the past 8 hours, please let us know.
- This next part of the visit should take about 20 minutes.

We will ask you to:

- Collect some of your urine (about 2 ½ ounces) in a cup we provide.
 - We may test your urine for chemicals that may be present in the environment.

We also would like to:

- Collect a small amount (about 3 tablespoons) of your blood by using a small needle.
 - We may test your blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment.

Number of Participants: 1,380

Duration: 1 hour (for the entire visit)

Explanation of burden this IC

On average, all components of Pregnancy Visits 1 and 2 impose about 1.5 hours per burden.

Sample collection takes place at Pregnancy Visits 1 and 2, each of which have their own ICs under ICRAS. We estimate 35 minutes of burden per respondent for the interview and SAQ components of Pregnancy Visits 1 and 2 (each) that are not specific to biospecimen and environmental sample collection.

Therefore, we compute that the average burden for biospecimen and environmental sample collection taking place at Pregnancy Visits 1 and 2 (listed under this IC) to be 1 hour per information collection.