OMB # 0925-0593

Expiration Date: July 31, 2013

Phase II

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

**Pre-Pregnancy Visit description (excerpted from VIS)**

*During the time before and during pregnancy, we will ask for your permission to collect blood and urine samples from you twice. During this visit, we would like to collect some samples from you.*

*We will ask you to:*

* Collect some of your urine (about 2 ½ ounces) in a cup we provide.
* We may use your urine for research studies that include biological, genetic and environmental testing based on the permission you gave during the Informed Consent process.

*We also would like to:*

* Collect a small amount (about 3 tablespoons) of your blood by using a small needle.
* We may use your blood for research studies that include biological, genetic and environmental testing based on the permission you gave during the Informed Consent process.

**Number of Participants:** 986

**Duration:** 15 minutes

\*\*\*\*\*

**Pregnancy Visit 1 description (excerpted from VIS)**

*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.

*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.

*We may collect environmental samples from your home, or we may provide you with kits so you can collect the samples yourself.*

* 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 ship them back to us in the pre-paid envelopes we provide.

**Number of Participants:** 3,712

**Duration:** 15 minutes

\*\*\*\*\*

**Pregnancy Visit 2 description (excerpted from VIS)**

*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 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.

*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.

*During the last part of this visit, we may collect environmental samples from your home, or we may provide you kits so you can collect the samples yourself.*

* + The environmental samples that will be collected are water samples from your faucet and dust from your vacuum cleaner.
* 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 ask that you collect the samples as soon as you can. After you have collected the samples, please ship them back to us in the pre-paid boxes we will provide.

**Number of Participants:** 4,599

**Duration:** 15 minutes