Questions and Answers about the Low Risk Ovarian Study (ID01-022):

1. ***What is the purpose of this study?***
   The purpose of this study is to see if a blood test, CA 125, may help to detect ovarian cancer early in post-menopausal women.

2. ***What is the CA 125 (Cancer Antigen 125) test?***
   The CA 125 is a blood test, which measures the concentration of CA 125 level in the blood stream. CA 125 is a glycoprotein antigen that is produced on the surface of cells and is released in the blood stream. The level is often found to be higher than normal in women with ovarian cancer. It can also be higher than normal in pregnancy, endometriosis, pelvic inflammatory disease, menstruation, acute and chronic hepatitis and other diseases such as gastrointestinal disease and pulmonary disease.

3. ***Can the CA 125 be elevated for reasons other than cancer?***
   Yes, it can be elevated in other non-cancerous diseases.

4. ***How much blood will be drawn?***
   The amount of blood drawn will be about 2 to 3 tablespoons.

5. ***How will I know the results?***
   The study coordinator or the nurse practitioner will notify you by phone or letter of your results.

6. ***What happens after I get the results?***
   Depending on the results, you may have to return in one year, three months or some participants will need a transvaginal ultrasound and a repeat blood test (CA 125). Based on the results of the transvaginal ultrasound and the blood test (CA 125), the participant will either return in three months or will be referred to a gynecologic oncologist or qualified healthcare professional.

7. ***What are the possible risks, side effects and benefits of taking part in this study?***
   Participants may experience pain, bleeding, and/or bruising from the blood draws. Very rarely, participants may faint and /or develop and infection with inflammation of the vein at the site where the blood is drawn.
   Transvaginal ultrasound has not been linked with any risks. Some women may feel discomfort during the ultrasound. Results from transvaginal ultrasound and/or blood tests may lead to surgery, which may or may not find cancer.

8. ***What kind of tests can be expected?***
   A blood test, possibly a transvaginal ultrasound, and if needed, further tests to be determined by your doctor.

9. What is a transvaginal ultrasound?

A transvaginal ultrasound is a test that uses sound waves to evaluate the position, size, and shape of the ovaries. A slender instrument is inserted into the vagina to help detect any abnormal areas. This test can be uncomfortable, not painful.

10. Who is paying for the CA 125 lab test?

The study will pay for study related CA 125 blood tests.

11. What if I had cancer?

You can participate as long as you are currently cancer free, and have not had any treatment (chemo, radiation, surgery) for the 12 months before you participate.

12. Can I participate if I'm taking hormones, Tamoxifen or Evista?

Yes, you can take those medicines and still participate.

13. What if I need a transvaginal ultrasound as a result of the CA 125 blood test results?

If the CA 125 results determine that you need a transvaginal ultrasound, you will be scheduled for one locally. Payment for transvaginal ultrasounds vary at each study site. The local study coordinator will review transvaginal ultrasound payment details with you when you go over the informed consent.

14. Why am I being asked to provide the name of a gynecologist or healthcare provider?

We will need the name to ensure that you receive adequate follow up if you need it.

15. Do I have to see a Gynecological Oncologist for follow up?

You have the option of either a gynecologic oncologist for follow up or a qualified healthcare provider of your choice.

16. Who will pay for a Gynecological Oncologist referral?

At this point, you may be considered a gynecological oncology patient. Therefore, your insurance will be billed for any further care required.

17. What if I see my own healthcare provider? Who will pay for that visit?

You or your insurance will pay for all visits to your own healthcare provider.

18. Can my provider receive a copy of my results?

Yes. You may provide or share a copy of the letter. You will also need to sign a medical information release form so we can send the information to your provider at any time.

19. Who will determine any further treatment?

Your provider, if necessary, will determine any further treatment. We can give you and your provider recommendations for further treatment, if necessary.

If you have any other questions or would like to participate in this study, contact the Low Risk Ovarian Study Team at(512) 324-8939 ordwh.research@dellmed.utexas.edu .