

**Copy of Patient Information Sheet:**



As part of standard of care, your physician is providing you with the HALO Pap Test for the Breast.

Your physician is also participating in a research data collection effort, the purpose of which is to gather data on the use of the HALO Test. The focus of the research is to help understand how the information provided by the HALO test impacts the management of breast health for all women who receive the test.

Your patient records, including the result of the HALO Test, will be reviewed and some limited data will be recorded on a research form. The health information gathered will be treated as confidential and will not include any personally identifiable information. It will include de-identified data like age and health status. There is a slight possibility that your health information may be viewed by the FDA and sponsor of the study. This may happen during the course of the study and is only done to make sure that the research is conducted and properly monitored.

There are no known risks to participating in this data collection effort.

You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this research.

There are no costs to participation, other than the regular cost of the HALO test itself. The sponsor of the data collection effort is NeoMatrix, the developer of the HALO Test. You will not be paid to participate in this study.

~~Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_~~

Your decision to be in this research is voluntary. You will not be penalized or lose benefits if you decide not to participate or decide to stop participating. You may cancel your permission to participate in this research at any time.

This is not a treatment study. Your alternative is not to participate in this study.

The database information may be analyzed to identify trends that may be used in scientific publication or presentations, but your identity will remain confidential. This permission will not end unless you cancel it. You may cancel it by sending written notice to your study doctor.

You may contact your study doctor or the Principal Investigator Matt Heindel with questions about the research or if you think you have been harmed as a result of joining this research. You can contact the Western Institutional Review Board (WIRB) if you have questions about your rights as a research subject at 1-800-562-4789. WIRB is a group of people who perform independent review of research.

I am informing my study doctor that I agree to participate in this research.

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_