SUBJECT NAME: _____

UNIT NUMBER: _____

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION AND CONSENT FOR PARTICIPATION IN A MIRAKIND/MIRADX RESEARCH PROJECT

TITLE: **Clinical investigation of the role of microRNA binding site mutations in cancer risk, prevention and treatment**

Funding Source:	**MiraKind/MiraDx, an independent research institute**
Principal Investigator:	**Joanne Weidhaas, MD, PhD**
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Address:	**MiraKind/Mira Dx** **11601 Wilshire Blvd., Suite 2410** **Los Angeles, CA 90025**

INVITATION TO PARTICIPATE AND DESCRIPTION OF PROJECT

You are invited to take part in a research study because you have been diagnosed with a cancer or have a family history of cancer.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will be available to discuss with you and answer any questions. Once you understand the study, you will decide if you want to participate; if so, you will be asked to sign this form. Your participation is entirely voluntary and the decision to join or not join the research study will not cause you to lose any medical benefits to which you are entitled and there is no penalty.

PURPOSE
The aim of this study is to study new genetic “markers” or “mutations” that predict the risk of developing cancer and which predict response and toxicity to cancer therapy. The markers being studied are found in the Deoxyribonucleic acid (DNA) in your body, called "germ-line DNA". The types of markers we are studying are variations or difference between your DNA and other people's DNA. We can test if you have these differences in a saliva/cheek swab collection from your mouth.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Up to 250,000 people may take part in this study through MiraKind/MiraDx.

PROCEDURES
Once it has been determined by your personal physician or through review of your application to join a MiraKind research study where you fit the study criteria, and you have reviewed the protocol, you will be given this consent form. After you have all of your questions answered, and decide to participate, and sign the consent form, you, or you and your physician will send in a DNA sample.

The study involves:

1) Salivary (Spit) Sample Collection or cheek swab sample collected by you or you and your physician and mailed to the MiraDx laboratory.
2) Variant Assay Test – Once the lab receives your sample, your DNA will be analyzed to determine if you have certain genetic variations.
3) Storage of Sample and Result - You may opt to allow MiraKind/MiraDx to use your DNA (genetic) sample to do further research. If you do not give us your explicit permission, your sample will be kept but de-identified, so that it can no longer be traced to you.
4) You may receive your individual results if requested directly and through a physician of your choice.
5) You may be enrolled through this consent in a registry, where you will be assigned a unique registry number and will be invited to complete surveys about your health history every 3 to 6 months. Any information you provide through registry surveys will be kept in a secure, encrypted database.

As a participant in this study, you should still continue to be followed as normally prescribed by your physicians for routine healthcare and screening.

RISKS AND DISCOMFORTS
This study does not involve a new treatment.

Risks of Spit Collection/Cheek Swab:

There are no reported risks associated with spit collection or cheek swab.

Risks of Data Collection and Privacy

There are no physical risks to you for donating and storing your clinical data for use in this study. However, there is a potential risk of a computer security breach, data breach, or unforeseen loss of privacy. Every effort will be made to keep your personal health information completely secure and confidential in this study. Please see the Confidentiality section for an explanation of how your information is protected below.

Known risks of a breach of confidentiality may include but are not limited to issues related to insurability or employability, or that family members may become aware of information related to the study and you, or that you may become aware of information about yourself or family members that you would have preferred not to know.

Risks of Genetic Testing

Your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic trait. If you choose to obtain individual results, the results may create stress or anxiety for you, or fear that there will be discrimination.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your individual results will be confidential, and only shared with your physician and you. They will never be disclosed to a third party without your explicit permission.

ECONOMIC CONSIDERATIONS
There can be a cost to obtain your individual results that is subsidized by MiraKind. You will not receive any payments for participating in this study.

BENEFITS
You will not benefit directly from this study, except through obtaining genetic information. We hope that the information we learn will increase our knowledge of human health and that this information will lead to better diagnoses and treatments in the future.

ALTERNATIVES
The alternative to being a part of this study is to not take part in this study.

CONFIDENTIALITY AND PRIVACY
Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases, information which will not be collected in this study.

When the results of the research are published or discussed in conferences, your name will never be associated with the publications or presentations, and no information will be included that would reveal your identity.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, MiraKind/MiraDx will receive information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, date of birth, address, etc. This information will be de-identified immediately after the sample is obtained and recorded, as you will be given a unique study number. The data manager and database builder at MiraKind and the staff at Miradx are the only individuals that will have a link that identifies you to your coded information, and this link will be kept secure.

Representatives from agencies such as the National Institutes of Health (NIH) or the Food and Drug Administration (FDA) may inspect study records during auditing procedures. However, these individuals are required to keep all donor information confidential. If you decide to participate in this study, you will be asked to authorize these uses and disclosures by signing this form. You must authorize these uses to participate in this study.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at MiraKind and MiraDx are trained to comply with HIPAA to ensure the confidentiality of your information. Both MiraKind and MiraDx have also implemented administrative and technical safeguards, such as encryption and password protection, to protect the security of all information collected in the study. You will immediately be notified if there were any breach to the confidentiality or security of your information.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

To help you make your decision to participate or not in this study, a MiraKind representative is available so that you can ask any questions you have about the research project. They can be contacted through the MiraKind website inquiry contact form, or directly through the email addresses or telephone number listed on the first page of this form. Sign the consent form only after you have had a chance to ask your questions and have received satisfactory answers from your physician, or a MiraKind staff member.

You may change your mind and decide to withdraw your permission for the sponsor to use health information from your medical records at any time by sending a written request to the principal investigator at the email address or MiraKind's address listed on the first page of this form. There is no penalty or loss of benefits to you.

If you withdraw your permission, your participation in the study will end. You can request that your DNA be destroyed at any point this same way. However, this withdrawal will not affect your future treatment or medical management in any way, and you will not lose any benefits to which you are otherwise entitled. The study staff will stop using your information for the trial, but information already collected up to the time you withdrew your permission will still be used for the study. Keeping your health information may be necessary to analyze the study results properly. Your part in the research may stop at any time for any reason, such as, the sponsor or the investigator decides to stop the study.

NEW INFORMATION

You will be told about any new information found during the study that may affect whether you want to continue to take part.

INVESTIGATOR INTERESTS

Dr. Weidhaas, the study principal investigator, has a proprietary interest in this research study (e.g. patent, trademark, copyright, or licensing agreement) with MiraDx. Due to this potential conflict of interest, Dr. Weidhaas will not be involved in the informed consent process or recruitment for this study. Dr. Weidhaas can answer questions about the study

outside of these roles. You can also speak with the enrolling doctor if you have additional questions.

QUESTIONS
We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully - as long as you feel is necessary - before you make your decision or if you have any questions at a later time. Please contact the principal investigator or study staff at the telephone number or email address listed on the first page of this form.

If you have any questions or complaints about your rights as a research participant contact Advarra IRB

- By mail: Study Subject Adviser Advarra IRB 6100 Merriweather Drive, Suite 600 Columbia, MD 21044
- Or call: 410-884-2900
- Or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00009633. An IRB is a group of people who review research projects to protect the rights and safety of participants.

WHERE CAN YOU GET MORE INFORMATION?
You may visit mirakind.org or miradx.org for more information about our organization and the aims of this study.

Optional use your genetic sample to do further research:

- ☐ I agree to have my DNA/RNA sample used for further research.
- ☐ I do not want my DNA/RNA sample used for further research.

AUTHORIZATION/CONSENT:
I have read this form and decided that _____ (printed name of subject) will participate in the study described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this signed and dated consent form if requested.

Signature of Participant: _____

Date _____

Printed Name of Consenting Physician: _____
(Dr. Weidhaas is the consenting physician if you are going directly through MiraKind)

Signature of Consenting Physician: _____
(Not necessary if you are going through MiraKind)

Date _____

Signature and Approval of Study PI: _____