Official title: Application of personalized minimal residual disease in predicting therapeutic efficacy in metastatic hormone-sensitive prostate cancer

NCT number: NCT07112612

Document date: January 8th, 2026

Instructions for Subjects

"Research projects involving the collection of blood, urine, feces, and other specimens from patients or healthy individuals" Instructions for Subjects Template

Project Name: Application of Individualized Minimal Residual Disease in Predicting Response to Treatment in Metastatic Hormone-Sensitive Prostate Cancer

Version number and date: V2.0, January 8th, 2026

Informed Consent Version Number Version Date: V2.0, January 8th, 2026

Research institution: The First Affiliated Hospital of Anhui Medical University

Principal Investigator (Responsible Research Physician): Sheng Tai

You are being invited to participate in a clinical research study. This notice is provided to you. This information may help you decide whether to participate in this clinical study. Please read it carefully and ask the researcher in charge of this study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the Institutional Ethics Review Committee.

Study objectives: Minimal residual disease (MRD), also known as measurable residual disease (MRD), refers to the presence of tumor after surgical resection (or other radical treatment) in the absence of imaging evidence of the disease. It is a new standard for assessing whether the tumor is "cleared". MRD-positive patients usually have a worse prognosis than MRD-negative patients and are considered a biomarker for determining prognosis. A study published by Professor Wu Yilong in "Cancer Discovery" in 2022 showed that the recurrence-free survival rate of people with persistently negative MRD tests reached 96.8%. Nonshedding tumors do exist before surgery, but they do not affect postoperative MRD monitoring. Currently MRD has been widely proven to be useful for monitoring the efficacy and evaluating the prognosis of perioperative patients. The main advantage of a reasonable MRD detection program is that it can provide more accurate and personalized detection reports based on the specific circumstances of each patient, which has an important impact on the early detection, treatment and prognosis evaluation of cancer.

Research process: It is expected that 50 subjects will participate in this study. Starting from the enrollment of the subjects, tissue will be punctured for WES testing before treatment, and 2 tubes (10ml/tube) of blood will be drawn for MRD testing before treatment. During the drug treatment, 2 tubes (10ml/tube) of blood will be drawn for MRD testing every 3 months until the completion of the study (the study duration is approximately one year). During this period, all samples will be used only for scientific research.

Risks and Discomfort: All your information will be kept confidential. Your sample will be collected in strict accordance with aseptic requirements. There may be some very small risks during specimen collection, including brief pain, local bruising, mild dizziness in a few people, or extremely rare needle infection.

Benefits: You will not receive immediate benefits from participating in this study, but MRD testing of your specimen will help predict the efficacy and prognosis of metastatic hormone-sensitive prostate cancer after drug use. This will help further promote the precision treatment of metastatic hormone-sensitive prostate cancer, may provide necessary advice for your treatment, or provide useful information for disease research.

Cost: MRD testing costs are borne by Shanghai Zhen Gu Biotechnology Company.

Compensation: No compensation

As a research subject, you have the following responsibilities: provide a true account of your medical history and current physical condition; tell the research doctor any discomfort you experience during the study; do not take restricted medications, foods, etc.(unlimited)Tell the study doctor if you have recently participated in or are currently participating in other research studies.

Privacy Issues: If you decide to participate in this study, All information about your research and individuals involved in research will be kept confidential. Your biological specimens will be identified by a study number, not your name. Personally identifiable information will not be disclosed to anyone outside the research team without your permission. All research team members and the study sponsor are required to maintain confidentiality regarding your identity. Your file will be kept in a locked cabinet and accessible only to researchers. To ensure the research is conducted in accordance with regulations, your personal data may be accessed by government regulatory authorities or members of the ethics review committee at the research site, as required. No personal information will be disclosed when the results of this study are published.

If you are harmed by participating in this study: You may receive free treatment and/or compensation for any damages related to this clinical study.

You may choose not to participate in this study, or notify the researcher at any time to request to withdraw from the study. Your data will not be included in the research results, and your medical treatment and rights will not be affected.

Disposal of biological samples and information after the study: After testing, excess biological samples will be directly destroyed by Shanghai Zhen Gu Technology Co., Ltd., and a destruction list will be provided, or they will be returned to the First Affiliated Hospital of Anhui Medical University (either option). These specimens may not be sent outside of mainland China without the approval of the First Affiliated Hospital of Anhui Medical University. The ownership of the submitted biological sample experimental data belongs to the First Affiliated Hospital of Anhui Medical University, which has the right to use the experimental data.

The study physician may terminate your participation in this study if you require additional treatment, if you do not comply with the study plan, if you develop a study-related injury, or for any other reason.

You can keep informed of the information and research progress related to this study at any time. If there is any new safety information related to this study, we will also notify you in a timely manner. If you have any questions related to this study, or if you experience any discomfort or injury

during the study, or if you have any questions about the rights of participants in this study, you can contact us through 15551418371 (*phone number*)and He Jun.

If you have any questions or concerns about your rights and health as a participant in this study, please contact the Ethics Committee of this institution at 62923102; Contact: Chen Yihao

Informed consent signature page

I have read this Informed Consent Form.

I had the opportunity to ask questions and all of them were answered.

I understand that participation in this study is voluntary.

I can choose not to participate in this study, or withdraw after notifying the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected.

The study physician may terminate my participation in this study if I require additional treatment, if I fail to comply with the study plan, if I develop a study-related injury, or for any other reason.

I will receive a signed copy of the Informed Consent Form.

Subject's name: _____

Subject’s Signature: _____

date:_____Year _____Month _____Day

I have accurately informed the subject of this document and asked him/her to read this informed consent form carefully and answer any questions or doubts raised carefully.

Researcher's Name: _____

Investigator’s Signature: _____

date:_____Year _____Month _____Day

（*Note: If the subject is illiterate, a witness signature is required; if the subject is incapable of acting, an agent signature is required.*）

Template for information for participants on "research projects involving the collection of patient tissue specimens"

Project Name: Application of Individualized Minimal Residual Disease in Predicting Response to Treatment in Metastatic Hormone-Sensitive Prostate Cancer

Version number and date: V2.0, January 8th, 2026

Informed Consent Version Number Version Date: V2.0, January 8th, 2026

Research institution: The First Affiliated Hospital of Anhui Medical University

Principal Investigator (Responsible Research Physician): Sheng Tai

You are invited to participate in a clinical research study. Due to clinical diagnosis or treatment needs, you need to undergo Prostate biopsy, some of the tissue removed during the operation may be discarded in addition to the tissue for routine clinical pathological examination. We will collect these remaining tissue specimens for the following research. This notice provides you with information to help you decide whether to participate in this study. Please read it carefully and ask the researcher in charge of this study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the Institutional Ethics Review Committee.

Study objectives: Minimal residual disease (MRD), also known as measurable residual disease (MRD), refers to the presence of tumor after surgical resection (or other radical treatment) in the absence of imaging evidence of the disease. It is a new standard for assessing whether the tumor is "cleared". MRD-positive patients usually have a worse prognosis than MRD-negative patients and are considered a biomarker for determining prognosis. A study published by Professor Wu Yilong in "Cancer Discovery" in 2022 showed that the recurrence-free survival rate of people with persistently negative MRD tests reached 96.8%. Nonshedding tumors do exist before surgery, but they do not affect postoperative MRD monitoring. Currently MRD has been widely proven to be useful for monitoring the efficacy and prognosis of perioperative patients. The main advantage of a reasonable MRD detection program is that it can provide more accurate and personalized detection reports based on the specific situation of each patient, which has a significant impact on the early detection, treatment and prognosis of cancer.

Research process: 50 subjects are expected to participate in this study. Starting from the enrollment of the subjects, tissues will be punctured for WES testing before treatment. Two tubes (10 ml/tube) of blood will be drawn before treatment for MRD testing. During the drug treatment, two tubes (10 ml/tube) of blood will be drawn every three months for MRD testing until the completion of the study (the study duration is approximately one year). During this period, all samples will be used only for scientific research.

Risks and Discomfort: All your information will be kept confidential. Your surgery will be performed by a professional surgeon, and we will only collect some tissue specimens for clinical pathology examination.

Benefits: You will not receive immediate benefits from participating in this study, but MRD testing of your specimen will help predict the efficacy and prognosis of metastatic hormone-sensitive prostate cancer after drug use. This will help further promote the precision treatment of metastatic hormone-sensitive prostate cancer, may provide necessary advice for your treatment, or provide useful information for disease research.

cost：The cost of MRD testing will be borne by Shanghai Zhen Gu Biotechnology Co., Ltd.

compensate: No compensation

As a research subject, you have the following responsibilities: provide a true account of your medical history and current physical condition; tell the research doctor any discomfort you experience during the study; do not take restricted medications, foods, etc.(unlimited)Tell the study doctor if you have recently participated in or are currently participating in other research studies.

Privacy Issues: If you decide to participate in this study, all information about your research and ongoing research your personal information will be kept confidential. Your tissue sample will be identified by a research number, not your name. Information that can identify you will not be disclosed to anyone outside the research team unless you give your permission. All research team members and research sponsors are required to keep your identity confidential. Your personal information will be kept confidential. Your file will be kept in a locked filing cabinet and accessible only to researchers. To ensure the research is conducted in accordance with regulations, your personal information may be accessed by government regulatory authorities or members of the ethics review committee at the research institution, as required. When the results of this study are published, no personal information will be disclosed.

If damage occurs related to clinical research, you can receive free treatment and/or appropriate compensation.

You may choose not to participate in this study, or notify the researcher at any time to request to withdraw from the study. Your data will not be included in the research results, and your medical treatment and rights will not be affected.

Research disposal of Biological Samples and Information After the Study: Excess biological samples after testing will be directly destroyed by Shanghai Zhen Gu Technology Co., Ltd., and a destruction list will be provided, or returned to the First Affiliated Hospital of Anhui Medical University (either option). These samples may not be sent outside of mainland China without the approval of the First Affiliated Hospital of Anhui Medical University. The ownership of the submitted biological sample experimental data belongs to the First Affiliated Hospital of Anhui Medical University, which has the right to use the experimental data.

The study physician may terminate your participation in this study if you require additional treatment, if you do not comply with the study plan, if you develop a study-related injury, or for any other reason.

You can keep informed of the information and research progress related to this study at any time. If there is any new safety information related to this study, we will also notify you in a timely

manner. If you have any questions related to this study, or if you experience any discomfort or injury during the study, or if you have any questions about the rights of participants in this study, you can contact us through 15551418371 (*phone number*)and He Jun.

If you have any questions or concerns about your rights and health as a participant in this study, please contact the Ethics Committee of this institution at 62923102; Contact person: Chen Yihao.

Informed consent signature page

I have read this Informed Consent Form.

I had the opportunity to ask questions and all of them were answered.

I understand that participation in this study is voluntary.

I can choose not to participate in this study, or withdraw after notifying the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected.

The study physician may terminate my participation in this study if I require additional treatment, if I fail to comply with the study plan, if I develop a study-related injury, or for any other reason.

I will receive a signed copy of the Informed Consent Form.

Subject's name: _____

Subject's Signature: _____

date:_____Year _____Month _____Day

I have accurately informed the subject of this document and asked him/her to read this informed consent form carefully and answer any questions or doubts raised carefully.

Researcher's Name: _____

Investigator's Signature: _____

date:_____Year _____Month _____Day

(*Note: If the subject is illiterate, a witness signature is required; if the subject is incapable of acting, an agent signature is required.*)

“Research projects must involve collecting medical history, data, epidemiological surveys, etc. from patients or healthy individuals.”

Subject Information Template

Project Name: Application of Individualized Minimal Residual Disease in Predicting Response to Treatment in Metastatic Hormone-Sensitive Prostate Cancer

Version number and date: V2.0, January 8th, 2026

Informed Consent Version Number Version Date: V2.0, January 8th, 2026

Research institution: The First Affiliated Hospital of Anhui Medical University

Principal Investigator (Responsible Physician): Sheng Tai

You are being invited to participate in a clinical research study. We have provided some information to help you decide whether to participate in this clinical study. Please read it carefully and ask the researcher in charge of this study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the Institutional Ethics Review Committee.

Study objectives: Minimal residual disease (MRD), also known as measurable residual disease (MRD), refers to the presence of tumor after surgical resection (or other radical treatment) in the absence of imaging evidence of the disease. It is a new standard for assessing whether the tumor is "cleared". MRD-positive patients usually have a worse prognosis than MRD-negative patients and are considered a biomarker for determining prognosis. A study published by Professor Wu Yilong in "Cancer Discovery" in 2022 showed that the recurrence-free survival rate of people with persistently negative MRD tests reached 96.8%. Nonshedding tumors do exist before surgery, but they do not affect postoperative MRD monitoring. Currently MRD has been widely proven to be useful for monitoring the efficacy and prognosis of perioperative patients. The main advantage of a reasonable MRD detection program is that it can provide more accurate and personalized detection reports based on the specific situation of each patient, which has a significant impact on the early detection, treatment and prognosis of cancer.

Research process: It is expected that 50 subjects will participate in this study. Starting from the enrollment of the subjects, tissue will be punctured for WES testing before treatment, and 2 tubes (10ml/tube) of blood will be drawn for MRD testing before treatment. During the drug treatment, 2 tubes (10ml/tube) of blood will be drawn for MRD testing every 3 months until the completion of the study (the study duration is approximately one year). During this period, all samples will be used only for scientific research. We will discuss the study with you or your family in detail. If you agree to participate, we ask you to provide information about your disease, including the course of your illness, family history, previous medical history, and any test results. We will assign a number to each participant and create a medical record.

Risks and Discomfort: It may be psychologically uncomfortable for you to communicate and talk with us.

Benefits: You will not receive immediate benefits from participating in this study, but MRD testing of your specimen will help predict the efficacy and prognosis of metastatic hormone-sensitive prostate cancer after drug use. This will help further promote the precision treatment of metastatic hormone-sensitive prostate cancer, may provide necessary advice for your treatment, or provide useful information for disease research.

cost: The cost of MRD testing will be borne by Shanghai Zhen Gu Biotechnology Co., Ltd.

compensate: No compensation

Privacy Issues: If you decide to participate in this study, your Participating in research and in research Your personal information will be kept confidential. The study physician and other researchers will use your medical information for research purposes. This information may include your name, address, phone number, medical history, and information obtained during your study visits. Your file will be kept in a locked filing cabinet and accessible only to researchers. To ensure the research is conducted in accordance with regulations, your personal information may be accessed by government regulatory authorities or members of the ethics review committee at the research site, as required. When the results of this study are published, no personal information will be disclosed.

If you are harmed as a result of participating in this research: You may receive free medical treatment and/or compensation for any harm related to clinical research.

You may choose not to participate in this study, or notify the researcher at any time to request to withdraw from the study. Your data will not be included in the research results, and your medical treatment and rights will not be affected.

The study physician may terminate your participation in this study if you require additional treatment, if you do not comply with the study plan, if you develop a study-related injury, or for any other reason.

You can keep informed of the information and research progress related to this study at any time. If there is any new safety information related to this study, we will also notify you in a timely manner. If you have any questions related to this study, or if you experience any discomfort or injury during the study, or if you have any questions about the rights of participants in this study, you can contact us through 15551418371 (*phone number*)and He Jun.

If you have any questions or concerns about your rights and health as a participant in this study, please contact the Ethics Committee of this institution at 62923102; Contact person: Chen Yihao.

Informed consent signature page

I have read this Informed Consent Form.

I had the opportunity to ask questions and all of them were answered.

I understand that participation in this study is voluntary.

I can choose not to participate in this study, or withdraw after notifying the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected.

The study physician may terminate my participation in this study if I require additional treatment, if I fail to comply with the study plan, if I develop a study-related injury, or for any other reason.

I will receive a signed copy of the Informed Consent Form.

Subject's name: _____

Subject's Signature: _____

date:_____Year _____Month _____Day

I have accurately informed the subject of this document and asked him/her to read this informed consent form carefully and answer any questions or doubts raised carefully.

Researcher's Name: _____

Investigator's Signature: _____

date:_____Year _____Month _____Day

(*Note: If the subject is illiterate, a witness signature is required; if the subject is incapable of acting, an agent signature is required.*)