| Clinical Protocol Form | | |
|---|---|---|
| Document Title | Document Description | Version No. |
| **TP-172-01** | **Informed Consent for Clinical Evaluation of an Intra-procedural 3D Needle Guidance Platform for Soft Tissue Tumors or Organs Requiring Percutaneous Biopsy as an Adjunct to Standard Image Guidance** | **1** |

**BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC**

**[Institution Name]**
**Research Consent Form**

**Protocol Title**: Clinical Evaluation of an Intra-procedural 3D Needle Guidance Platform for Soft Tissue Tumors or Organs Requiring Percutaneous Biopsy as an Adjunct to Standard Image Guidance
**Protocol #**: TP-172
**Sponsor**: Mediview XR, Inc.

**Principal Investigator**:
**Institution**:
**Address**:
**Telephone**:

In this document, "I/my/you/your" mean the participant you are giving permission to join the study.

---

**KEY INFORMATION ABOUT THIS RESEARCH STUDY**

Please read this form or have this form read to you. Take your time to make your decision. Make sure we explain the study to you. Ask us any questions. You may also want to talk about the study with your doctor and family, loved ones, or friends. The choice to join the study, or not, is yours. If you decide to join, please sign and date this form.

**Why is this study being done?**
You are being asked to join a research study that is being done by [INSERT PI NAME], sponsored by MediView XR Inc. We hope to learn about the usability of a new augmented reality guidance system for minimally invasive procedures. You are being asked to join because you are scheduled for a minimally invasive soft tissue biopsy as a part of your standard of care.

**Important information for you to think about:**

- **What am I being asked to do?** As a part of your biopsy procedure, you are being asked to allow providers to collect research data (overall procedure time, accuracy, etc.) on a augmented reality navigation device designed to help operators identify the lesion for biopsy.

- Your participation is voluntary. If you choose to participate, you will be randomly chosen to undergo a biopsy procedure with or without the use of an augmented reality navigation device in addition to standard-of-care ultrasound and CT. Data about the length of your procedure, needle placement, and complications will be recorded. If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.

- **How long will the study last?** If you join the research study, your participation will not increase the length of time that would normally be required for a biopsy procedure. No extra visits are required as a part of this study.

- **Any possible risks or discomforts?** There are not expected to be any physical risks to you as part of this study that would differ from the standard of care. The study device (XR90) is an addition to standard of care guidance. There are risks for any biopsy procedure as a part of standard of care. You will sign a separate consent form for your biopsy procedure.

**Confidentiality Risks**

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential using the following safeguards: If you decide to be in this study, a research coordinator will receive information that identifies you and your personal health information. Any information that can identify you will remain confidential and will be de-identified so that others cannot directly identify you. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

- **Will this study help me?** The study is intended to compare the benefits of the XR90 navigation device when used with ultrasound and CT for guidance to ultrasound and CT alone. The device is intended to increase provider confidence and decrease overall procedure time. If you are randomly selected to have XR90 used during your procedure you may experience a decrease in the overall procedure time.
- **Do I have to join?** You do not have to be in this study. You will still receive your procedure should you decide not to participate in this study.

**Costs**

- The study sponsor will provide the study device at no charge to you. Your biopsy procedure will not be paid for by the sponsor.

**This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent form, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.**

**If you are now or have been (within the last 6 months) in any other research study, please tell the research team.**

**What will I be asked to do?** You will be asked to sign an informed consent and media release which allows the research staff to record your images and videos of the procedure. No personally identifiable information will be recorded, and all images will be de-identified. Images and videos will be recorded for teaching or educational purposes only.

You will then undergo a standard-of-care soft tissue biopsy procedure in interventional radiology. During the procedure, after undergoing anesthesia, you will be randomized to one of two groups, Group A or Group B. You will have an equal chance of being assigned to either group, like flipping a coin. If you are randomized to Group A, your provider will use standard-of-care ultrasound and CT plus XR90 for guidance during your procedure. If you are randomized to Group B, your provider will use standard-of-care ultrasound and CT for the procedure without XR90. Both you and the study doctor will have no say in whether you get assigned to Group A or Group B. Data will be collected on the procedure, but no additional steps will be required by you as the participant.

Participating in this study does not require any additional blood work or genetic testing.

If you are pregnant or may be pregnant, please inform your provider, you will not be able to be a part of this study.

**Do I have other choices?** Yes, you may choose to undergo your soft tissue biopsy without participating in the study. No data will be collected during your procedure and the study device will not be used for guidance.

**Who will be in the study?** A total of 102 people will be asked to enroll in this study at 3 different sites. 34 people will be asked to join the study at [Institution name].

Your participation in this study is expected to last 1 day.

**New information that may change your decision to join:** During the study, we will tell you if there is new information or changes to the study that could affect you, your health, or your desire to stay in the study.

**What are the risks?** There are risks of stress, emotional pain, inconvenience, and possible loss of privacy and confidentiality when joining this research study. There are not expected to be any additional physical risks that would not normally occur during a biopsy procedure.

**What about pregnancy?** Pregnant women are not allowed to participate in this study.

**What if I am harmed?** For medical emergencies, call 911. If you are injured or become sick because of joining this study, you will have to pay for any emergency treatment. The hospital will not pay for these services.

If you have been injured or become sick because of taking part in this study, tell the researcher right away. If you have any questions or believe that you have been treated carelessly in the study, please contact: [enter site-specific contact]

The Sponsor, MediView XR, Inc., will pay for care if you are injured or sick because of being in this study.

If you are injured or sick because of being in this study, the Sponsor will pay for care to diagnose and treat the injury if:

(1) You have private health insurance; the Sponsor will pay for the costs that are denied or not otherwise paid for by your insurance company.
(2) You do not have any health insurance; the Sponsor will pay for the costs; and
(3) You have Medicare or Medicaid, claims for the costs will first be submitted to the Sponsor for payment, and any remaining balance not paid for by the Sponsor will be submitted to Medicare or Medicaid, applying Medicare and Medicaid billing rules and regulations.

If you are injured or sick because of being in this study, the sponsor will only pay for care if the study was properly performed. The sponsor will not pay for injuries caused by your pre-existing condition unless that condition was made worse by being in the study.

Medical care will not be paid if you are injured or ill because of being in the study if it is because you purposefully did not follow instructions in this consent form or instructions from the researcher or if it is because of the natural progression of an underlying or pre-existing condition.

No other compensation will be offered by the sponsor or [Institution name] or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

**Can being in this study help me?** Being in this study may or may not help you; however, we hope that the information learned will help improve interventional techniques, decrease complications that occur during the procedure, and decrease the length of needle-based procedures.

**How will my information be used and protected?** We will take steps to protect your personal information, but we cannot promise the confidentiality of all research data. The Principal Investigator and MediView XR, Inc. will carefully monitor study procedures to protect the safety, quality of the data, and integrity of the study. All data will be securely stored by MediView XR, Inc. within an electronic data capture and clinical data management tool. Only investigators and the sponsor who have access to the database will access data relevant to the study.

All relevant research data will be archived for two years after final reporting, publication of the project, or post-market approval. Research data will be stored on MediView XR, Inc.-

maintained servers longer if required by an institution or regulatory bodies.

The WCM, Georgetown, and MedStar researchers for this project, the Institutional Review Board (IRB), the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS), designated researchers from MediView XR Inc, and the Food and Drug Administration (FDA) may access your records.

We will share your information with a court of law or the government, in the unlikely event this is required by law.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

Clinically Relevant Research Results

As the results obtained during the research study are for research purposes only and are not for medical diagnosis, you will not receive individual results. In some circumstances, if the study doctor learns information related to your health from the study procedures, the study doctor will discuss this information and your options with you.

**Will my information be used in the future?** All information that identifies you (e.g., your name, and date of birth) will be removed from the data collected in this project. We will keep your de-identified information in a library that has information from other research studies. Your information may be used in the future for other research studies without your permission. Information that cannot identify you or be linked to you will be kept for a long period of time (longer than 50 years). Some of your information may be placed on scientific databases for others to use. These may include databases maintained by the federal government. These data cannot be removed from the library.

**Will I be paid?** You will not be paid.

**Do I have to join? Can I quit the study?** It is your decision whether to join this study or not. You have the right to choose not to join or to stop your participation at any time. Your decision to join in this research or stop participating will not affect your regular care nor your relationship with your doctors, or other employees.

You will be told about new information that may affect your health, well-being, or participation in this study.

**What are the costs?** There are no direct costs for being in this research study.

**Will I get the study results?** Medical information collected during the research, such as diagnostic CT images, may be entered into your electronic medical record and will be available to clinicians and other staff who provide care to you. Images and videos recorded during the procedure will not be added to your electronic medical record.

**Will I be able to see or copy my information?**
During this study, you will be able to see or copy your protected health information as described in this form per your healthcare institution's policies. During your participation in this study, you will have access to your research record. You will not have access to the images and videos that are recorded as part of this study during your standard of care procedure.

**AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION**
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research.
- Records about your study visits
- Information obtained during this research about laboratory test results.
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations, and medical history.

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies that are responsible for protecting your rights.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA, and other regulatory authorities. Reasons you

may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

**CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS**
If you have any questions, concerns, or complaints about the research, please contact your study doctor:

[PI NAME:
PI ADDRESS:
TELEPHONE:
EMAIL:]

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns, or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

**Refusal to Sign**
If you choose not to sign this consent form and permission for the use and disclosure of your PHI, you cannot be in the research study. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with, your doctors, or other employees.

**Signature**

I agree to participate in this research and allow my information to be used in this research. My questions have been answered. I will get a signed copy of this form.

**STATEMENT OF CONSENT - SIGNATURES**

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

| _____ | _____ | _____ |
|---|---|---|
| Name of Adult Participant | Signature of Adult Participant | Date |

Please initial one of the following:

____ I agree to be audio and video recorded.
____ I do not want to be audio and video recorded.

**Witness to Consent of Participants Who Cannot Read or Write**

I confirm that the consent form was presented orally to the participant in the participant's own language, the participant was given the opportunity to ask questions, and the participant has communicated consent to participate (initial below):

____ Making his/her mark above
____ Other means; Indicate here: _____

_____
Signature of witness for adults unable to read or write

| _____ | _____ |
|---|---|
| Name of witness for adults unable to read or write | Date |

**Participant Medical Record Number: _____**

**Researcher Signature** (to be completed at time of informed consent)

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

| _____ | _____ | _____ |
|---|---|---|
| Name of Research Team Member | Signature of Research Team Member | Date |