

Permission to Take Part in a Human Research Study

Title of Research Study: Randomized Controlled Trial of Home Semen Testing in Men Beginning Attempts to Conceive

Principal Investigator:

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Supported By: This research is supported by Northwestern University.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to participate in this research study because you are beginning attempts to conceive.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are assessing the use of at-home semen testing to improve the diagnosis of male fertility.

Home semen testing will be performed via the YoSperm® device, a commercially available FDA-approved device to assess semen parameters via smart device (<https://yospermtest.com/>). In addition, the YoSperm® technology enables patients to send results directly from their device to their provider via secure email.

How long will the research last and what will I need to do?

We expect you to be in this research study for 365 days (1 year).

You will be randomly put in one of two groups by chance (like the flip of a coin). One group will undergo at home semen testing. The other group will receive standard of care treatment.

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All participants will complete electronic surveys to measure your overall wellbeing in addition to attitudes and beliefs about fertility.

More detailed information about the study procedures can be found under the section **What happens if I say “Yes, I want to be in this research”?**

Is there any way being in this study could be bad for me?

There is no risk to participants in this study from the testing or questionnaires. There is a small potential for anxiety when completing questionnaires or after obtaining results of semen testing. There is potential risk using the YoSperm® app, since there is no method of data transmission over the internet that is 100% secure.

More detailed information about the risks of this study can be found under **“Is there any way being in this study could be bad for me? (Detailed Risks)”**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include early detection for male infertility.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 694-9001.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irbcompliance@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 200 people will be enrolled in this study at our institution.

What happens if I say “Yes, I want to be in this research”?

A complete list of all timepoint and procedures are listed below.

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PROCEDURES INVOLVED:

Visit 1 – Screening

Participants will complete an intake questionnaire about demographics and health status, a questionnaire to measure your overall wellbeing and a questionnaire to measure your attitudes towards fertility. At this visit, the participants will be randomized to either home semen testing or standard of care.

Visit 2 – Home semen testing

Patients randomized to home semen testing will be given a test to complete at home. The patient will send home semen test results to the study team via the application. Patients will complete the post test survey to evaluate their experience with the test. Patients randomized to standard of care do not complete the at home semen testing.

Three-months. Six-months and twelve-months after visit one

Participants randomized to either at home semen testing or standard of care will complete three questionnaires to evaluate their overall wellbeing and attitudes towards fertility.

What are my responsibilities if I take part in this research?

Participants who are selected to undergo home semen testing will be required to complete the testing and submit their results. They will complete a survey to evaluate their experience after testing.

Participants randomized to either at home semen testing or standard of care will also be responsible for completing electronic surveys at the time of their initial appointment and at three, six, and 12-month intervals.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator to remove you from the research study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

While participating in the study, the risks, side effects, and/or discomforts include:

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- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.
- Loss of confidentiality
- YoSperm® app may not work or malfunction

To minimize these risks, the following actions will be taken:

- While completing the survey, you can tell the researcher that you feel uncomfortable or do not care to answer a particular question.
- We will keep all study related information in a secure database that is only accessible to study personnel.
- Participants will have access to YoSperm® Customer support.

There also may be other side effects that we cannot predict.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: "What happens to the information collected for the research?".

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include early detection of semen parameter abnormalities, which can lead to early diagnosis and treatment of male infertility.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures

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required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **“What happens to the information collected for the research?”**.

If you agree to take part in this research study, patients will be compensated \$20 for participating at the time of enrollment. An additional \$20 will be compensated at the time of study completion. This will be provided in the form of a giftcard.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or

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affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

PI's Name: Joshua Halpern, MD MS
Institution: Northwestern University
Department: Department of Urology

Address: 675 N St Clair St #150, Chicago, IL 60611

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You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Signature Block for Adult Capable of Providing Consent:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent