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Participant Information Sheet – Semen Testing for Screening Purposes

Company sponsoring the research study:	Max Biocare
Name of chief investigators:	Dr Carolyn Ee Professor Alan Bensoussan Dr Jennifer Hunter Professor William Ledger Dr Andrew Davidson
Name of other investigators:	Professor Caroline Smith Mr Mahmoud Al-Dabbas Mr. Paul Fahey
Address of research site:	NICM Research Health Institute Building J Western Sydney University Westmead Campus 158-160 Hawkesbury Rd Westmead
Phone numbers:	+61 2 4620 3085 or +61 414 357 363 (out of hours/emergency contact)

Project Title: A clinical study of the effect and safety of Hominax to improve sperm health.

Protocol ID: Max Biocare003

We are seeking your permission to take two semen tests as part of the screening process for Sperm Health study conducted by Dr Carolyn Ee from NICM at Western Sydney University. It is a key eligibility requirement for participants who are willing to participate in Sperm Health study and may benefit from a potential new treatment for sperm health.

This Participant Information form tells you about our Clinical research study and explains what is involved in semen testing, which is a key eligibility requirement for all potential participants. Knowing what is involved will help you decide if you want to take part in the research. Participation in this research is voluntary, and you are free to withdraw at any time. Any unprocessed information you have given us will be withdrawn upon your request. Please read through this information carefully and contact the researchers if you have any questions (contact information can be found at the end of this information sheet).

What is the purpose of this study?

This is a clinical research study designed to evaluate the safety and effect of Hominax capsules (given by mouth) for improving sperm health. At the moment, Hominax is considered an experimental supplement as it is unknown if it has an effect on sperm health. However, it is thought that Hominax may decrease damage to sperm and improve sperm production.

When sperm are produced in low numbers, are abnormally shaped, or are not able to move well, this may reduce the ability of sperm to penetrate and fertilise an egg.

This study will measure the number, shape and ability of your sperm to move well to determine the effect of the study treatment.

Hominax contains ingredients that are all approved for human consumption and use in complementary medicines by the Australian Therapeutic Goods Administration (TGA, and is listed on the Australian Register of Therapeutic Goods for sale in Australia.

How many other people will be in the study?

There will be approximately 50 people enrolled in this study. The study is being done at several different research sites in Australia. Approximately 10 people will be enrolled at this site.

How long will participation in this study last?

Study duration is for approximately 26 weeks. There are four study visits including Screening, Week 0 (Start of Study), Week 16 and Week 24 involve visiting the clinic. Research nurse/officer will also follow up with you over the phone at Week 2 and Week 26 respectively. If you decide to take part in this study, we will ask you to sign this consent form before we do any study related activities.

Why am I being asked to have semen tests?

We are asking your permission to take two semen tests 7-21 days parts at the time of screening to determine your eligibility to be enrolled in this research study. Eligibility will be determined according to results from these semen analyses. Only men who have been previously tested for semen and informed that their sperm health could be better will be eligible to have 2 semen tests at the time of screening. Please note that having the semen tests done does not mean you are enrolled in the Sperm Health Study. Your eligibility to take part in the Sperm Health Study depends on the results of your semen tests.

Screening

During the screening, you will be asked to have the following tests and procedures:

- The research nurse/officer will contact you over the phone to check you satisfy the study inclusion/exclusion criteria.
- Once potential eligibility is determined, she will mail you the screening package that will include the participant information sheet, consent form and 2 request forms for semen analyses.
- You will be required to take your first semen tests by providing a fresh semen sample by masturbation for analysis at a specialised fertility clinic. Please observe 3–7 days of sexual abstinence (either sexual intercourse or masturbation) prior to your semen test.
- There is no cost to you for having the semen test taken.
- Please note that taking this test does not guarantee that you will be enrolled in the study.
- Based on the result of your first semen analysis, you will be instructed to take an appointment for your second semen test.
- The interval between the two semen tests should not be less than 7 days or more than 3 weeks
- By the end of the screening visit, the study doctor will determine if you are eligible to continue into the study.
- If you will not be able to continue in the study, the study doctor will explain why and will discuss with you other treatment options.

- If you are confirmed as suitable participant for the study then you will be enrolled in the study and scheduled to return for your Week 0 (Start of Study) visit approximately two weeks after the screening visit.

What are the risks of having the screening done?

It is highly unlikely that your test result will be a cause for concern. However, should this occur, there could be 3 scenarios for your semen test results.

1. Eligible → this means your sperm health could be improved (there are one or more abnormalities in shape, movement or concentration)
2. Sperm count too low → you will be referred to a doctor to discuss (your fertility specialist or your GP)
3. Sperm count normal → no action needed

If you are already undergoing a fertility treatment, then your fertility specialist will be informed with your consent.

What are the possible benefits of having the screening done?

While we cannot guarantee that having two semen tests will entitle you to take part in the study, you will receive information on your sperm health. There is no cost to you for having these tests taken.

Will I be eligible to take part in the Sperm Health study after having these tests done?

We cannot guarantee this as your ability to take part in the study depends upon your semen test results. If your semen test result allows you to go ahead to the next step of screening in the study, there are still several steps before we can confirm you are able to take part. You are then considered finally eligible to take part in the study if your sperm parameters fit the diagnostic criteria applicable to the study.

Our research officer/research nurse will discuss this process with you during screening.

What will happen to my test samples?

Samples of your semen tests will be taken by a specialised fertility clinic. Your samples will not be sold, and will be stored securely in the laboratories for seven days and then destroyed.

What will happen to information about me?

We require the following information from you to order two semen tests:

- Your Initials
- Date of birth
- You will be given a screening ID number.

You will be identified by your screening ID number. Your information will be kept confidential and lab results will be de-identified before being reviewed by GP/Specialist in order to confirm your eligibility. Your records obtained before and after getting enrolled in the study, as well as related health records, will remain strictly confidential at all times. However, these may need to be made available to others working on behalf of NICM Western Sydney University, Max Biocare, the Human Research Ethics Committee members and Medicines Regulatory Authorities.

By signing the consent form you agree to this access for the current study and any further research that may be done. However, we will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected. Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

Please note that the minimum retention period for data collected in a clinical research study in Australia is 15 years. The information you supply or about you will be stored securely and it will be de-identified before it is made to available to any researcher outside the study team.

Can I have access to my semen tests results?

In accordance with the relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. Please contact the study team member named at the end of this document if you would like to access your information. We can also forward your results to your general practitioner if you wish. Please speak to our research team if you wish this to happen.

Are there any special instructions to follow while in this study?

Prior to providing a semen sample, you must abstain from sexual activity (either sexual intercourse or masturbation) for between two-to-three and seven days. In order to reduce variability between semen tests, we strongly encourage you to keep the abstinence period the same for both your semen tests. That is, if you abstained for 3 days for the first test, try as much as you can to abstain for exactly 3 days (no more, no less) for the second test. This may ensure that your test results are similar.

What happens if I am injured as a result of taking part in this research study?

While Max Biocare does not expect you to suffer any health problems by taking part in this trial, Max Biocare may compensate anyone whose health suffers as a result of participation in this trial. You do not have to prove it was anyone's fault; if the health problem arose because of your participation in this trial, you will be compensated.

Is being in the study voluntary?

Participation in this research study, and in this component of the study, is completely voluntary. You are under no obligation to have the semen tests taken. However, it may mean that you are not eligible to take part in the study.

If you withdraw or are removed from the study, biological samples (for example, blood or semen samples) that have been collected from you can be withdrawn if they have not yet been analysed or destroyed. If you want your samples withdrawn, you must tell the study team before or at the time you leave the study.

What will I have to pay for if I take part in this research study?

There will be no charge to you for your participation. The costs of your semen tests will be covered by the research study.

If I take part in this research study, how will my privacy be protected?

With your consent your family doctor (General Practitioner) will be told that you have decided to take part in this study.

If you are already undergoing a fertility treatment, then your fertility specialist will be informed with your consent.

What specific benefits will I receive for participating in the study?

It is possible that sperm health may improve because of study treatment or because of your visits to the research site. However, there is no guarantee that you will benefit in any way. Information from this study may help other people in the future.

How is the study being paid for?

The study is being sponsored by Max Biocare Pty Ltd an Australian registered company.

What if I require further information?

Please contact Dr Carolyn Ee on 02 4620 3085 or Mahmoud Al-Dabbas on 0414 357 363 should you wish to discuss the research further before deciding whether or not to participate.

What if I have a complaint?

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H11411.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email humanethics@uws.edu.au. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

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Participant Consent Form: Screening

This is a project specific consent form. It restricts the use of the data collected to the named project by the named investigators.

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I acknowledge that:

1. I have read and understood the Patient Information Sheet dated 20 March 2018 for the above Study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw without giving any reason, without my medical care or legal rights being affected.
3. I understand that others working on NICM Western Sydney University and Max Biocare's behalf, the Independent Ethics Committee and Medicines Regulatory Authorities will need my permission to look at my health records both in respect of the current Study and any further research that may be conducted in relation to it, even if I withdraw. I agree to this access.
4. I consent to participate having two semen tests to determine my eligibility for this research study. A written copy of the information has been given to me to keep.
5. I consent to the collection, processing, reporting and transfer within Australia of my personal and sensitive data for healthcare and/or medical research purposes.
6. I agree not to restrict the use of any data or results, which arise from this Study.
7. I agree to take part in the above Study.

_____
Printed name of subject

_____ _____
Signature of subject Date
Please date your own signature at the time of signing.

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Printed name of investigator obtaining consent

Signature of investigator obtaining consent Date

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