Title of research study: Ejaculation latency in men who have sex with men

Investigator: Alan W. Shindel, MD, MAS

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you have identified as a man who has anal sex with a male partner (or partners) at least once a week.

What should I know about a research study?
(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed and devices to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a copy of this document.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, you may talk to the Principal Investigator or the Research Coordinator at (916-734-6498).

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Information to help you understand research is on-line at http://www.research.ucdavis.edu/IRBAdmin. You may talk to a IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- 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 subject.
- You want to get information or provide input about this research.

Why is this research being done?
We are interested in learning more about the sexual lives of men who have sex with men (MSM). The more health care providers know about MSM sexuality the better equipped the medical establishment will be to provide culturally sensitive care to MSM who have sex-related concerns or problems.
How long will the research last?
We expect that you will be in this research study for 10 weeks.

How many people will be studied?
We expect about 150 men here will be in this research study out of 250 people in the entire study nationally.

What happens if I say yes, I want to be in this research?
If you decide to participate in this research our study team will meet with you either in person or over the phone for to collect brief demographic and health information. As this is a research study that involves you and your sexual partner it is required that both of you agree to participate; you cannot enroll in this sexuality research project if your partner does not want to participate.

You and your partner(s) will be assigned a linked ID number to safeguard your identities; after you have that number we will not need to use your name or other identifying information when communicating about the study and its results.

After you have been enrolled, the study team will provide you with a stop watch and a paper diary on which to record your ejaculation latency time (ELT, the period of time between when you penetrate your partner during sex and time when you start to ejaculate).

You will be instructed on how to record ejaculation latency time by the research team. After enrolling, for the first 4 weeks the partner who is usually the top (insertive partner) will record his ELT during each episode of anal sex. For the second 4 weeks, the partner who is usually the bottom (receptive partner) will record his ELT during each episode of anal sex.

We request that you record ELT in this fashion even if you sometimes switch top and bottom roles. You do not need to record your ELT for oral sex (penis to mouth sex, giving or receiving) with your partner. After you have completed the 8 week study you will send your results (marked only with your ID number to help protect confidentiality) to the research team by U.S.

No drugs or biological agents will be given to you. There will be no blood draws. There is no need for in-person follow up nor for any additional visits with the research team. You may record ELT values wherever you usually have sexual activity.

What happens if I do not want to be in this research?
You may decide not to take part in the research and it will not be held against you.

What happens if I say yes, but I change my mind later?
You can leave the research at any time and it will not be held against you.
Is there any way being in this study could be bad for me?
There are no physical risks from participating in this research study aside from the general risks that come along with sexual activity such as sexually transmitted infections (STI). We encourage you to use safe sex practices at all times (i.e. routine testing for STI and Human immunodeficiency virus (HIV), condoms, know your partners, etc).

You and/or your partner might feel some embarrassment or discomfort from measuring your ejaculation latency; this might have an impact on your sexual life.
There is a slight privacy risk from participating. The research team takes your privacy seriously. Only members of the research team will have access to the information you provide. Your ID code will be used in all correspondence so as to separate the ELT data from anything that could be used to identify you personally.

This study does not involve legal risks.

Will being in this study help me in any way?
This study will not directly help you in any way. However, it may help improve the ability of doctors to provide care for MSM who have sexual health concerns in the future.

What happens to the information collected for the research?
Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study. We will not be accessing your protected health information (e.g., your medical record). We will only have access to medical data that you provide to us when you enroll.

What else do I need to know?
It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury.

You will not be compensated for taking part in this study. Data collected as part of this survey will likely be presented (after removal of any identifying information) at medical society meetings and possibly in scientific reports in medical journals.
Are there other research opportunities?
If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional.
(______) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _________________________________.

Signature Block for Capable Adult
Your signature documents your permission to take part in this research.

_________________________  _________________________
Signature of subject        Date

_________________________
Printed name of subject

_________________________  _________________________
Signature of person obtaining consent    Date

_________________________
Printed name of person obtaining consent