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Proposal No. _____

INFORMED CONSENT FOR MEDICAL & CLINICAL STUDIES
KSU-IRB Form 005-E
King Saud University, Riyadh, Kingdom of Saudi Arabia

SECTION A:

STUDY INFORMATION

Study Title:	**Assessment of the Effect of Vitamin E Supplementation on the Ocular Tear Film**
Protocol Number/Study Code:	
Principal Investigator:	**Dr. Meznah Saud Almutairi**
Principal Investigator Address:	**King Saud University – College of Applied Medical Sciences** **Building 11 , 3rd floor, Office # 246**
Telephone:	**0555404272**
Email:	**mzalmutairi@ksu.edu.sa**
Sponsor/Non-Commercial Funding	**King Saud University**

INTRODUCTION

Dear Participant,

You are invited to voluntarily participate in the above-mentioned local research study. A research team member will explain what the study involves and how it will affect you. Before signing this form, please carefully review all aspects of the study to make an informed decision. This consent form outlines the study procedures, the risks and benefits of participation, and how we will maintain your confidentiality. Please take your time to ask questions and feel comfortable deciding whether to participate. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form and will receive a copy for your records. Throughout the course of this study, you will have the right to ask any questions about the study or your medical condition. As part of the consenting process, we will keep you updated on any new findings that might affect your decision to continue with the trial.

SECTION B:

1. WHAT IS THE PURPOSE OF THE STUDY?

The purpose is to assess the impact of vitamin E supplementation on tear film parameters, including subjective symptoms of ocular dryness (SPEED questionnaire) and objective measures of tear film stability, volume, and quality, in healthy adults.

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2. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 64 healthy adults aged 19-30 years will participate.

3. STUDY LOCATION?

The study will be conducted at the Optometry Clinics of the College of Applied Medical Science at King Saud University.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

- If you participate, you will:
- Provide written informed consent.
- Be screened against inclusion/exclusion criteria.
- Take one JP Natural Vitamin E 400 IU (268 mg of natural alpha-tocopherol; 30 softgel capsules) daily for 3 consecutive days.
- Attend two visits:
- **Visit 1 (Baseline):** Complete the SPEED questionnaire, then undergo tear film assessments • (NITBUT, TMH, TF):
- The noninvasive tear breakup time (NITBUT),
- Tear meniscus height (TMH),
- Tear ferning (TF) tests
- **Visit 2 (Follow-up):** Repeat the same assessments 24 hours after the third dose.

5. During the course of this study, you will go through the following visits/ procedures.

➢ **Visit 1 (Baseline):**

- SPEED questionnaire (dry eye symptoms). This short questionnaire (about 8 questions) asks how often and how severely your eyes feel dry, gritty, or irritated. You simply select the answer that best applies to you — it takes about 2–3 minutes and does not involve any physical examination of your eyes.

- Non-invasive tear breakup time (NITBUT): to measure the stability of the tear film. A small device that does not touch your eye (EasyTear View+) is held near your face. You will blink normally, then keep your eyes open as you normally would; the device measures, in seconds, how long your tear film stays smooth before small dry patches appear. The test takes only a few seconds, involves no eye drops, and does not touch your eye.

- Tear meniscus height (TMH): measures the volume of the tear film. Using the same EasyTear View+ device, we take a photograph of the thin line of tears along your lower eyelid and measure its height in millimeters. This also takes only a few seconds, does not touch your eyes, and is completely painless.

Tear ferning (TF): We will collect a small tear sample (approximately 1 µL) from the lower meniscus of the eye using a glass microcapillary tube (10 µL). We will observe and capture TF images with an Olympus DP72 and evaluate them using the five-point TF grading scale. This is a quick, gentle procedure (about one minute): the fine glass tube briefly touches only the tear film

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at the edge of your lower eyelid and does not touch the surface of your eye, so it is painless. The tiny sample is then dried and examined under a microscope; you don't need to do anything further.

- **Supplementation:** Take one JP Natural Vitamin E 400 IU (268 mg of natural alpha-tocopherol; 30 softgel capsules) daily for 3 consecutive days.
- **Visit 2 (24 hours after the third dose):** Repeat SPEED, NITBUT, TMH, TF.

6. HOW LONG WILL I BE IN THE STUDY?

The study will last about 4 days for each participant (baseline visit, 3 days of supplementation, and a follow-up visit 24 hours after the last dose).

7. WHAT IS EXPECTED OF ME DURING THE STUDY? WHAT ARE MY RESPONSIBILITIES?

Your participation in this study is entirely voluntary, and you may withdraw at any time without providing a reason and without affecting your healthcare benefits or your relationship with the study staff. Signing this informed consent form does not mean that you waive your legal rights, yet you will still have the following responsibilities:

i) Read the informed consent form and seek an understanding of the study.
ii) Ask questions and understand your rights.
iii) Follow all directions about tests and procedures carefully, and appear for the study visit as scheduled, i.e., be on time for the clinic, and if you have any circumstances that prevent you from being on time, please inform your study staff.

8. CAN I STOP BEING IN THE STUDY?

You can decide to stop participating in the study at any time. Please inform the principal investigator about your decision to stop. No one will try to coerce you to continue.

8. ARE THERE RISKS IF I STOP BEING IN THE STUDY?

There are no risks at all if you decide to stop being in this study.

9. WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

There are no risks or side effects to participating in this research study, as all tests and procedures are non-invasive. Also, taking Natural Vitamin E 400 IU (268 mg of natural alpha-tocopherol; 30 softgel capsules) daily for 3 consecutive days is well tolerated; therefore, no significant side effects or risks are expected.

10. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Participants will undergo a comprehensive assessment of the tear film (quality and quantity).

11. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

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There is no risk of injury during this study. In case you have any questions, you may call Dr. Meznah Almutairi at +966-555404272.

12. WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?

None.

13. WILL I BE PAID FOR MY TAKING PART IN THIS STUDY?

You will not be compensated for your time spent during data collection.

14. WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

All the information collected in subjects' records belongs to King Saud University and the study Sponsor. Your records will remain strictly confidential and will not be made publicly available. However, in some situations, as the study requires, your information may be provided to relevant personnel or permitted under KSU IRB regulations or applicable laws within the limitations and boundaries of Saudi Arabia's national, Sharia and ethical laws. Scientific data from this research project may be presented or published in the journal, but your personal identity will always remain protected.

SECTION D:

15. WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to 'take part' *or* 'not to take part' in the study. You may leave the study at any time during your participation. No matter what you decide, you will not be penalized and will not lose any regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from KSUMC. However, Dr. Meznah Almutairi may use information collected before or after you leave the study. If you are injured because of this study, you do not lose any of your legal rights to seek payment by signing this form. For further information regarding your rights as a participant, you may call the office of the Institutional Review Board, King Saud University, at +966-11 469-1529 to 32.

16. WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Before you agree to be in this study, you will talk to a study team member qualified to tell you about this study. You can ask questions about any aspect of the research. If you have further questions about the study, you may ask them at any time. You may call Dr. Meznah Almutairi at +966-11 8058114.

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SECTION E:

SUBJECT'S CONSENT

The research and procedures have been explained to me. I have been allowed to ask any questions, and all of them have been answered. I have read the consent and have had time to think about participating. I can ask any additional questions I may think of later. I may refuse to participate in the study, and I may quit the study at any time without penalty and without affecting my health care.

i) I have been given permission for the study doctor and sponsor to use and disclose my personal health information.

ii) I will receive a signed copy of this consent form.

iii) I agree to participate in this study. My agreement is voluntary. I do not have to sign this form if I do not want to be part of this research study.

Subject Signature:	
Date:	
Time: (AM ☐ PM ☐)	

Person Obtaining Consent:

I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent:	
Date:	
Time: (AM ☐ PM ☐)	
Principal Investigator:	
Signature of Principal Investigator:	
Date:	
Time: (AM ☐ PM ☐)	

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