

**Form for approval of research at the Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**The researchers listed below request approval for the following research protocol:**

Submission Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Version Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- | --- |
| Telephone Number | Email | Israeli ID Number | Student's Full Name |
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| Email Address | Telephone Number | Research Advisor: |
|  | 026291958  (If advisor is outside of the college, telephone number must be supplied) |  |

**האם המנחה אישר את הקובץ הסופי טרם ההגשה במודל?** לא - כן: תאריך אישור\_\_\_\_\_\_\_\_\_\_\_

Location of Reseach: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project Title (Hebrew)**

**Project Title (English)**

**Introduction:** Provide a reference for each fact stated. The introduction is a literature review which is short and selective. Provide only the information necessary for the reviewers to understand the project goals, the rationale for undertaking the research, and its importance. Maximum length: 11/2 pages

**Research Hypothesis and Goal:** what is the goal of the research and why

**Methods:**

**Subjects:** Number of recruited subjects, recruitment pool (clinics, a particular department, etc.), age range, gender. For example: XX volunteers (TT male, SS female), between the ages of UU-VV will be recruited from the Department of Optometry's Refraction Clinic. YY eyes will be included in the analysis.

**Inclusion and Exclusion Criteria:** Specify if special populations are included (such as children < 18 years of age, pregnant women, persons suffering from a particular disease or taking a particular medication, and so on). Example: Volunteers will be free of ocular pathology and not taking medications with known ocular side effects. Pregnant women will not be included.

Subjects will be recruited from the student body at Hadassah Academic college and/or patients presenting at the Hadassah Academic College Eye Clinic. Patients will only be approached at the completion of their examination. Their participation or lack thereof will not affect their clinical treatment or examination and they will be tended for by clinical staff that are not involved in the research study.

If you publish an ad in college and / or on Facebook or anywhere else, the text of the ad should be placed in the appendix.

All examinations will take place in the refraction clinics at the Department of Optometry, Hadassah Academic college. The methods will be written and orally explained to the participants and they will sign a statement of informed consent prior to their participation (for children- assent and guardian consent).

**Duration of Procedures:** X minuates for each patient. How long should each participant expect the procedures to last (minutes).

**Procedures:** Describe the stages of the research project in chronologiccal order, including who will be performing each examination.

**Expected Findings:** expected outcomes and why

**Statistical Analysis:** Describe the outcome variables and the statistical test employed to examine significance. Differentiate between statistical significance and clinical significance. Example: the distance visual acuity will be converted to LogMAR scale and will be compared with and without refractive correction using a Student's paired t-test with p<0.05 considered significant.

**Potential Side Effects or Risks**: All risks associated with the project and the means for reducing or treating them, including simple discomfort or fatigue. For example, all procedures performed are standard optometric procedures undertaken during visual examinations. As such, potential side effects are no different from a standard clinical optometric examination and include eye strain, eye fatigue, general fatigue, dry eye.

Other side effects that can be caused while using lenses include dryness and dryness of the eyes, itching, discharge, hypersensitivity to light and swelling of the eyelids. In exceptional cases, a rupture of the lens, corneal abrasions, corneal edema, corneal vasculature, inflammation of the cornea, inflammation of the conjunctiva, or any other unusual side effect, the use of the lens will be discontinued and the participant will contact examiners for further treatment (Which usually includes referral for eye examination in the optometry clinics).

Each participant may contact the research authors and discontinue their participation in the study at any time.

**Clinical follow-up program:** None. (if yes-please describe, for example there is a follow-up, etc.). For example, if abnormal test results were found, to which the subject was not aware, he would refer to comprehensive tests at the optometry clinics.

You may choose to cease your participation in the study at anytime without any consequences.

**Study Duration:** X months- forms and approvals, X months- data collection (procedures), X months- analysis, X months- write up

[ ] If study lasts longer than a year, must renew the application after 11 months.

**Confidentiality:** Results will only be used for research analysis and your personal details or infomration will not be disclosed. You will only be referenced by a random serial number/ initials.

**Researchers requesting exemption from statement of informed consent**

[ ] Yes. If yes, describe why\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Example: Retrospective study with anonymous files

[ ] No

**Appendix**

1. Appendix A: Signatures
2. Appendix B: Consent Form in all languages necessary. Participant and explaining researcher must sign two forms. One form is given to the participant and the other is kept with the researcher.
3. Appendix C: Bibliography according to requested format

**Appendix A: Signatures**

– **I hereby acknowledge and accept the responsibility for protecting the rights and welfare of all participating subjects in accordance with the described protocol and institutional policies and procedures. Furthermore, I certify that:**

* NO involvement of human subjects in this project will begin before written approval of the Committees for the Protection of Human Subjects has been received.
* Any additions or changes to this protocol will require the submission of a Request for Revision form and for the review and approval by the Ethics Committee prior to initiation.
* I will renew my application after 11 months, if necessary.
* I weighed the risk and discomfort to the benefit ratio and took into account the welfare and well-being of the volunteers.
* I will explain all the procedures and risks to the participants prior to obtaining their informed consent.
* I will not deprive participants of treatment if they choose not to participate or to leave the study at anytime.
* I will maintain participant anonymity and any defining characteristic of participants. This information will be available to qualified study personnelle only.
* Written documentation of any unanticipated problems or injuries connected with an approved protocol must be provided to the Ethics Committee within 5 working days.
* All signed consent documents will be retained for at least 1 years past the completion of the research activity. (Note: Faculty sponsors are responsible for retaining signed consents for student projects.)
* Signing this document does not relieve me of responsibility for the wellfare and well being of my participants.

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| --- | --- | --- |
| **Date** |  | **Researcher Name** |
|  | Electronic Signature |  |
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Ethics Committee Member Signatures:

|  |  |  |
| --- | --- | --- |
| **Date** |  | **Name** |
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**Appendix B:**

**Consent Form**

Use language that can be understood by a lay-person. No jargon and professional terminology,

We would like to invite you to participate in a research study taking place at the Department of Optometry, Hadassah Academic College.

The study goal is to compare/ examine/measure XXXX. The procedures entailed in this study are not different from a standard visual examination. Procedures are non invasive and not painful and include XXXXXXX visual examinations, and various examinations that test how well the lens inside your eye can help you focus at targets held close-up, ocular health, …

Side effects due to the study are not different from side effects experienced during standard optometric examinations, and include eye strain, eye fatigue, general fatigue…

You may withdraw at anytime without any penalties.

You will be asked to come in for XX days/visits/hours, YY hours per visit.

You will not be payed for your participation/you will be paid TT for your participation as well as travel expenses. In addition, you will receive UUUU gratis.

The results of this study are for research purposes only and your name will not be used in presentations of the findings.

We would very much appreciate if you agreed to participate.By signing below, you are agreeing to paritipcate in the study as explained both orally and in the above. By signing, you are acknowledging that all of your question pertaining to the study have been answered.

1. I understand that informed consent is required of all persons participating in this project.  
2. All procedures have been explained to me and all my questions have been answered to my satisfaction.  
3. Any risks and/or discomforts have been explained to me.

4. Any benefits have been explained to me.  
5. I understand that, if I have any questions, I may contact XXX (PHONE NUMBER)  
6. I have been told that I may refuse to participate or to stop my participation in this project at any time before or during the project. I may also refuse to answer any question.  
7. All information that is obtained in connection with this project and that can be identified with me will remain confidential as far as possible within legal limits. Information gained from this study that can be identified with me may be released to no one other than the investigators. The results may be published in scientific journals, professional publications, or educational presentations without identifying me by name.  
  
I HAVE READ (OR HAVE HAD READ TO ME) THE CONTENTS OF THIS CONSENT FORM AND HAVE BEEN ENCOURAGED TO ASK QUESTIONS. I HAVE RECEIVED ANSWERS TO MY QUESTIONS. I GIVE MY CONSENT TO PARTICIPATE IN THIS STUDY. I HAVE RECEIVED (OR WILL RECEIVE) A COPY OF THIS FORM FOR MY RECORDS AND FUTURE REFERENCE.  
  
Subject Name (printed):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone of Researcher for any quesitons or side effects:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of student(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Advisor(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Must sign two copies, give one to participant and maintain one for study records!**

**במידה והמחקר מבוצע בשפה אחרת (עברית, ערבית וכד) יש לספר טופס הסכמה נוסף בכל שפה**

**C: Bibliography**

**Every cited study must appear in the bibliography, and vice versa.**

**Reference:**

Family name Capital. (year). Name of paper. *Name of journal in Italic style*, 48, volume, pages.

For example:

Menon RS, Ogawa S, Strupp JP, & Ugurbil, K. (1997). Ocular dominance in human V1 demonstrated by functional magnetic resonance imaging. *Journal of Neurophysiology*, 77, 2780-2787.