Institutional Review Board Approval for Research

Standard Operating Procedures for
Johns Hopkins University School of Medicine Wilmer Faculty at King Khaled Eye Specialist Hospital

Background:

With Johns Hopkins Medicine (JHM) increasingly diversifying around the globe, a greater number of Johns Hopkins faculty find themselves in foreign countries. Research is an important part of the collaboration between the Johns Hopkins faculty and host country researchers, and should be encouraged by facilitating the interaction where possible.

An example of such collaboration is the current arrangement between Johns Hopkins University School of Medicine Wilmer Eye Institute (Wilmer) and King Khaled Eye Specialist Hospital (KKESH). Wilmer faculty live in Saudi Arabia and work at KKESH, and are part of the network of research collaborations that are starting up with funding from Saudi Arabia and elsewhere. Wilmer faculty plan to serve as Principal Investigator (PI) on research studies being conducted at KKESH, and also to serve as co-investigators on research being conducted by KKESH PIs.

The purpose of this document is to provide a set of standard operating procedures (SOP) that will be used by Wilmer faculty conducting human subjects research at KKESH, describing the compliance training and Institutional Review Board (IRB) requirements at JHM and KKESH for these studies.

I. SOP for Training Certification

All Wilmer faculty conducting human subjects research at KKESH must have completed the required JHM IRB compliance training (including HIPAA training). Wilmer faculty serving as a PI on a research study conducted at KKESH must also complete the additional JHM IRB compliance training requirements for PIs (as described on the JHM IRB website). The Director of Research at KKESH will ensure that each faculty member who wishes to engage in human subjects research has up to date certification.

II. SOP for Wilmer faculty who are serving as co-investigators on studies with a KKESH PI conducted solely in Saudi Arabia

- For studies conducted solely in Saudi Arabia with a KKESH PI and Wilmer faculty as co-investigators, the KKESH IRB will serve as the IRB of record. The JHM IRB and KKESH IRB will enter into an IRB Authorization Agreement for these studies (see Appendix 1). A separate eIRB application will not be required by the JHM IRB.

- For new studies that have not been submitted to the KKESH IRB, Wilmer faculty may be listed as co-investigators on the KKESH IRB application. For studies that have already been approved by the KKESH IRB and now want to add Wilmer faculty as co-investigators, the KKESH PI will amend their KKESH IRB application to include the
Wilmer faculty. These applications will be submitted to the KKESH IRB for review and approval.

- Wilmer will track these KKESH research studies that include their faculty as co-investigators. The Wilmer faculty co-investigator at KKESH will send a copy of the KKESH IRB approval notice, along with the KKESH IRB application, cover page, abstract and approved consent form to the designated contact at Wilmer for tracking (see Appendix 3 for the KKESH IRB application form). If Wilmer has questions or concerns about the research study, they have the prerogative to further clarify any concerns and determine whether it is appropriate for Wilmer faculty to participate in the research at KKESH.

III. SOP for Wilmer faculty at KKESH serving as PI on a research study conducted at KKESH

- For studies conducted with Wilmer faculty serving as PI on a research study conducted at KKESH, the JHM IRB will serve as the IRB of record. The JHM IRB and KKESH IRB will enter into an IRB Authorization Agreement for these studies (see Appendix 2). JHM IRB approval will be contingent upon receiving local ethics review and approval by the KKESH IRB Chair. If the KKESH IRB Chair determines that full KKESH IRB review is required, the study will be referred to the KKESH IRB for review.

- The Wilmer faculty PI will initiate an eIRB application with a JHM IRB/KKESH international consent form (includes altered HIPAA statements for the international context) (see Appendix 4). When the JHM IRB determines that the study may be approved, they will issue an approval with administrative changes, pending the local ethics review and approval by the KKESH IRB Chair.

- After the KKESH IRB Chair conducts the local ethics review of the research and approves it, the KKESH translation team will translate the consent form. The Wilmer faculty PI will submit the translated consent form and certificate of translation (or translation letter from the KKESH translation team) to the JHM IRB to receive final JHM IRB approval of the research.
Appendix 1 – IRB Authorization Agreement with JHU relying on KKESH

Name of Institution or Organization Providing IRB Review (Institution/Organization A):
King Abdullah Eye Specialist Hospital (KAESH)
FWA #: FWA0001757
IRB Registration #: 001 with National Bioethics Council of Saudi Arabia

Name of Institution Relying on the Designated IRB (Institution B):
John Hopkins University School of Medicine

The Officials signing below agree that John Hopkins University School of Medicine may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one)

☐ This agreement applies to all human subjects research covered by Institution B’s FWA.
☐ This agreement is limited to the following specific protocol(s):

Name of Research Project: ____________________________
Name of Principal Investigator: ________________________
JHU IRB Protocol #: ________________________________
Sponsor or Funding Agency: __________________________
Award Number, if any: ______________________________

☐ Other (describe): Human subjects research conducted in Saudi Arabia with KAESH staff serving as Principal Investigators and JHU SOM faculty serving as co-investigators

The review performed by the designated IRB(s) will meet the human subject protection requirements of Institution B’s OHRP-approved FWA. The IRB(s) at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the terms of its OHRP-approved FWA. The John Hopkins School of Medicine IRB(s) will rely upon KAESH’s determinations regarding compliance with local requirements.

This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution A):

Print Full Name: Jason Al-Dhubi, MD
Address: KAESH, Riyadh, Saudi Arabia
Institutional Title: FWA/IRB Chairman
Date: 4/24/12
Email: JasonA@jhsph.edu

Print Full Name: Deepak Edward, MD
Address: KAESH, Riyadh, Saudi Arabia
Institutional Title: Research Director
Date: 4/3/12
Email: deepak@kaesh.edu

Signature of Signatory Official (Institution/Organization B):

Print Full Name: Daniel E. Ford, M.D., M.P.H.
Address: 721 N. Broadway, Suite 115, Baltimore, MD 21205
Institutional Title: Vice Dean for Clinical Investigation
Email: jhamas@jhmi.edu
Date: 4/3/12
Appendix 2: IRB Authorization Agreement with KKESH relying on JHU

Name of Institution or Organization Providing IRB Review (Institution/Organization A):
Johns Hopkins University School of Medicine

IRB Registration #: IRB 1 - IRB00000025, IRB 2 - IRB00001555, IRB 3 - IRB00001656, IRB 5 - IRB00000026,
IRB 6 - IRB00000026, IRB X - IRB000013794

Federalwide Assurance (FWA) #, if any: FWA00005752

Name of Institution Relying on the Designated IRB (Institution B):
King Khaled Eye Specialist Hospital (KKESH) Federalwide Assurance (FWA) #, if any: FWA00017557

The Officials signing below agree that King Khaled Eye Specialist Hospital may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one)

( ) This agreement applies to all human subjects research covered by Institution B's FWA.

( ) This agreement is limited to the following specific protocol(s):

Name of Research Project: __________________________________________
Name of Principal Investigator: ______________________________________
JHIM IRB Protocol #: __________________
Sponsor or Funding Agency: __________________ Award Number, if any: __________________

( ) Other (describe): Research conducted at KKESH with JHUSOM faculty serving as principal investigator

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB(s) at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. The Johns Hopkins School of Medicine IRB(s) will rely upon KKESH's determinations regarding compliance with local requirements.

This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution A):

[Signature]
Date: 4-16-12

Print Full Name: Daniel E. Ford, M.D., M.P.H. Institutional Title: Vice Dean for Clinical Investigation
Address: 733 N. Broadway, Suite 115, Baltimore, MD 21205 Email: jhmirb@jhmi.edu

Signature of Signatory Official (Institution/Organization B):

[Signature]
Date: 4-24-12

Print Full Name: Hassan Al-Dhibi, MD Institutional Title: HEC/IRB Chairman
Address: KKESH, Riyadh, Saudi Arabia Email: hddhibi@kkesh.med.sa

Print Full Name: Deepak Edward, MD Institutional Title: Research Director
Address: KKESH, Riyadh, Saudi Arabia Email: dedward@kkesh.med.sa
Appendix 3: KKESH IRB Application
Date ______________________________

RP No. ____________ Title: __________________________________________________________________________

PI Code: ______________

Date of Research Council Approval: ________________________________

Please attach copy of the letter of approval from the Research Council

Sponsor ________________________________

Protocol Version __________________________

Investigator’s Brochure Version and Date __________

Informed Consent Version ________________________

Other ________________________________

1. Principal Investigator (must be KKESH staff or collaborating staff)

Name: ________________________________ Signature: ________________________________

KKESH Academic Title: ________________________________

KKESH Clinical/Administrative/Research Appointment(s): ________________________________

Telephone Extension: __________ Email: __________________________ Pager No. ________

Human Studies Certificate: □ Yes □ No If yes, details of the certificate (name and duration):

2. Co-Investigator (may be KKESH or another institution)

a) Name: ________________________________ Signature: ________________________________

Institutional Affiliation: ________________________________

Institutional Academic Title: ________________________________

Institutional Clinical/Administrative/Research Appointment(s): ________________________________

Telephone Extension: __________ Email: __________________________ Pager No. ________
b) Name: ___________________________  Signature: ___________________________
Institutional Affiliation: ________________________________
Institutional Academic Title: ________________________________
Institutional Clinical/Administrative/Research Appointment(s): ________________________________
Telephone Extension: __________ Email: ___________________________ Pager No. ________
Human Studies Certificate: □ Yes  □ No  If yes, details of the certificate (name and duration):

c) Name: ___________________________  Signature: ___________________________
Institutional Affiliation: ________________________________
Institutional Academic Title: ________________________________
Institutional Clinical/Administrative/Research Appointment(s): ________________________________
Telephone Extension: __________ Email: ___________________________ Pager No. ________
Human Studies Certificate: □ Yes  □ No  If yes, details of the certificate (name and duration):

d) Name: ___________________________  Signature: ___________________________
Institutional Affiliation: ________________________________
Institutional Academic Title: ________________________________
Institutional Clinical/Administrative/Research Appointment(s): ________________________________
Telephone Extension: __________ Email: ___________________________ Pager No. ________
Human Studies Certificate: □ Yes  □ No  If yes, details of the certificate (name and duration):

e) Name: ___________________________  Signature: ___________________________
Institutional Affiliation: ........................................

Institutional Academic Title: ............................................................

Institutional Clinical/Administrative/Research Appointment(s): ........................................

Telephone Extension: ............... Email: ................................. Pager No. ............

Human Studies Certificate: □ Yes □ No If yes, details of the certificate (name and duration):

f) Name: ______________________________ Signature: ______________________________

Institutional Affiliation: ............................................................

Institutional Academic Title: ............................................................

Institutional Clinical/Administrative/Research Appointment(s): ........................................

Telephone Extension: ............... Email: ................................. Pager No. ............

Human Studies Certificate: □ Yes □ No If yes, details of the certificate (name and duration):
KING KHALED EYE SPECIALIST HOSPITAL

Project Abstract for Research Proposals

Type of Study:  □ Laboratory  □ Clinical

STRUCTURED ABSTRACT OF PROPOSED WORK (between 150-200 words):

• Purpose/Background  • Methods  • Utilization

RESEARCH PROPOSAL: Please fill in details under each section. Please refer to research department guidelines while completing each section.
PROJECT DESCRIPTION:

A. BACKGROUND
B. SPECIFIC AIMS/OBJECTIVES
C. EXPERIMENTAL DESIGN AND METHODS
D. MANAGEMENT AND WORK PLAN
E. UTILIZATION
King Khaled Eye Specialist Hospital
Human Ethics Committee/Institutional Review Board Application Form

1. Nature of Study (check only one)
   □ Exclusively case report
   □ Exclusively retrospective chart review
   □ Predominantly retrospective chart review with some patient recall/updated examination
   □ Predominantly prospective patient enrollment with some retrospective data collection
   □ Exclusively prospective patient enrollment

   Please provide a brief synopsis of the project:

2. Select type of review requested:
   □ Expedited, why?
   □ Exempted, why?
   □ Full Board Review?

3. Sample size, Source of Patients and Length of Study
   Will this research involve intervention / interaction with participants?
   □ Yes □ No

   Estimated Length of Study?

   Recruitment Sources:
   □ Hospital participants
     □ Inpatient
     □ Outpatient
     □ OR
     □ Employee
     □ Others (please specify)
     □ Pediatric
   □ Prior study participants who have consented to be contacted for future research
   □ PI or co-investigator patients
   □ Referrals from other physicians
   □ Participant referrals/peer or network recruiting

4. Participant Information:
   a. Will you obtain identifiable data, records, specimens, or samples, or have access to codes, links or identifiers?
   □ Yes □ No

   b. Age ranges of participants (e.g., 0-17, 18-100):

   c. Study population – check all that apply:
      □ Male adults (18+)
Female adults (18+)
□ Male children (<18)
□ Female children (<18)

d. Will pregnant women be excluded from this study?
□ Yes □ No

e. Special Study Populations – check all populations that may be enrolled:
□ Adults lacking capacity to consent
□ Non-viable neonates/neonates of uncertain viability
□ Prisoners
□ Non-English speakers
□ Children who are in foster care or wards of the state

f. Will you enroll healthy volunteers?
□ Yes □ No

5. Support information:
Check all sources of support (pending or awarded):
□ Monetary
□ Material or equipment
□ None of the above

6. Study includes (check all that apply):
□ Current approved medications that will be used for recognized indication
  List __________________________________________
  __________________________________________
  __________________________________________

□ Current approved medications that will be used “off line”
  List __________________________________________
  __________________________________________
  __________________________________________

  Please provide rationale for “off line” use along with supporting literature data

□ Investigational medications
  List __________________________________________
  __________________________________________
  __________________________________________

  Please provide summary of previously published information regarding efficacy and side effects, along with a relevant bibliography

□ Current approved surgical procedures that will be used for recognized indications
□ Current approved surgical procedures that will be modified for “off line” use
List __________________________________________
__________________________________________
Please provide rationale for “off line” use along with supporting literature data

□ Investigational procedure
List __________________________________________
__________________________________________
Please provide summary of previously published information regarding efficacy and side effects, along with a relevant bibliography

□ Current approved technical device that will be used for recognized indication
List __________________________________________
__________________________________________

□ Current approved technical device that will be used “off line”
List __________________________________________
__________________________________________
Please provide rationale for “off line” use along with supporting literature data

□ Investigational technical device
List __________________________________________
__________________________________________
Please provide summary of previously published information regarding efficacy and side effects, along with a relevant bibliography

□ Human Biological Samples
7. Study Location

☐ KKESH
☐ KKESH with another institution, please specify: ____________________________

8. Risks

Does the study expose the patient to extra risks other than those associated with normal management of the patient’s condition: ☐ Yes ☐ No

Does this study involve appreciable risk to the patient’s social well-being? ☐ Yes ☐ No

Does this study involve appreciable risk to the patient’s psychological well-being? ☐ Yes ☐ No

Does the study involve invasive procedures not part of normal management of the patient’s condition? ☐ Yes ☐ No

If yes, please specify

A. Additional risks to the patient

B. The rationale for which this patient was selected for inclusion in this study and exposure to additional risk

C. The potential benefit of information gained from exposure to the additional risk by either the patient or other similarly affected individuals in the future.

D. The potential benefit to the advancement to medical knowledge.

Please provide summary of published data on risks associated with this study, along with a relevant bibliography (attach to this form)

Medicolegal Liability Risk (check one)

☐ None ☐ Minimum ☐ Moderate ☐ Severe

Institutional and Cultural Liability Risk

Does this study conflict with institutional interests? ☐ Yes ☐ No

Does this study conflict with local culture? ☐ Yes ☐ No
Does this study conflict with the Islamic religion? □ Yes □ No

Does the PI or any study team member (or their spouse, domestic partner, or dependent children) have a financial interest (e.g., royalty, equity, consulting, employment) or fiduciary relationship (e.g., board service) with the sponsor and/or manufacturer of products used in this research? □ Yes □ No

9. Consent and Waivers
a. Check the type of consent planned for this study:
   □ Patient Information Sheet and Written Consent
   □ Informed Oral Consent
   □ Written Consent
   □ Oral Consent
   □ Consent Waiver

Who will obtain Consent? _________________
Who will give Consent?
□ Patient
□ Patient Representative
□ Both

Will Participants receive Compensation?
□ Yes □ No
If yes, how much? Payment Schedule? _______

Will you advertise for Participants? □ Yes □ No
If yes, a copy of the material needs approval and mention in the protocol.
Type of advertisement _________________

10. Devices
a. Will any investigational or marketed medical device(s) be studied in this research?

11. Data Confidentiality
a. I confirm that all the procedures listed below will be used to protect the confidentiality of data and samples collected and stored for research purposes:
   • Only authorized persons will be granted access
   • Only authorized persons may enter and view study data
• Passwords and system IDs will not be shared
• Physical security of the workstations/files will be maintained
• Adequate back-up plan is in effect
• Staff trained on data entry system and importance of security procedures
• Workstations with databases will not be left unattended

b. Will a certificate of Confidentiality be obtained for this study?

Investigator Pledge/Certification

If approved, I pledge to:

• Conduct this study in accordance with the stated protocol and in full compliance with KKESH Policy and Procedure 389-005: Human Ethics Committee/Institutional Review Board.
• Make no modifications of the stated protocol without the expressed written approval of the HEC/IRB.
• Take full responsibility for the conduct of the co-investigators participating in this project.
• Inform the HEC/IRB and Research Department of all changes in co-investigators, including additions and deletions.
• Provide all patients with a copy of the approved patient information sheet in their preferred language.
• Submit signed “Consent to Participate in Research” and “Consent to Participate in Genetic Research” (if applicable) to the Research Department file.
• Place the “Informed Consent for Participation in Research Project” in the patient medical record, including the project number, principal investigator, and project title.
• Not apply undue pressure upon potential subjects to enroll in the study.
• Permit subjects to leave the study for any reason without jeopardizing their future care at KKESH.
• Report all serious complications, in writing, to the HEC/IRB within one week of occurrence.
• Submit the mandatory progress report on or before the date specified by the HEC/IRB.
• Cooperate fully with Monitoring Unit of the HEC/IRB during periodic project review.
• Cease all activity on this project if requested to do so by the HEC/IRB or the Chair, HEC/IRB.

Principal Investigator:

_________________________  ___________________________  ___________________________
Printed Name   Signature   Date
Appendix 4: KKESH Consent Form
Instructions for developing informed consent/privacy authorization document

Please call the JHM IRB office at 410-955-3008 (from inside the United States) or at 00-1-410-955-3008 (from Saudi Arabia), if you have any questions

Drafting the Consent Form

This February 2012 version consent form template is to be used for studies that will be reviewed by the JHM IRB and conducted at the King Khaled Eye Specialist Hospital in Saudi Arabia.

Shaded Instruction Boxes:

Many sections of this document include brief instructions to provide a general overview of information required in the section. **Please delete all shaded instruction boxes before submitting your consent form to the JHM IRB for review.** To delete, select a shaded box and click the cut button on the Word toolbar.

Section Headings:

- 14 point font [Times New Roman is preferred font]
- Section headings marked *Insert if applicable* may be omitted if they do not apply to your study. If sections are omitted, the paragraphs should be renumbered.

Text:

- 12 point font [Times New Roman is preferred font]
- Suggestions/hints for the text to be written under each heading are included and instructions are shaded blue.
- **Please delete all shaded instruction boxes before submitting this form.** To delete these shaded boxes, click the “cut” icon in the toolbar at the top of the document.

Header:

- To insert the date of the consent form, the Principal Investigator’s name and the application number (for new studies the application number may not be available to you and can be left blank) into the Header, go to the Toolbar, select View, select “Header and Footer.” After inserting your information, select Close.

Tips on Pagination:

- Once the text of the consent document is complete, format the page numbers. In Microsoft Word, start by clicking on File on the toolbar. Then, click on Print Preview. If, in Print Preview, the numbers do not reset appropriately, return to the document. *Make sure you are not in a “track and change” mode. Go to the toolbar, select View, select “Header and Footer”, and then select the footer option. Highlight the page number, right click to select “Update Field.”*
Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Protocol Description:
- The portions of the consent form that are specific to the study must conform to the protocol.
- Individuals taking part in the study should be referred to as participants, not patients.
- The use of the second person (e.g., “You will receive…”) is generally required;
- The use of the first person (e.g., “I understand that…”) is generally not allowed.
- Guidelines for avoiding common errors in consent forms are on page 3.

Required Paragraphs:
- The International HIPAA Privacy Authorization developed by the General Counsel must be included in all consent forms.
- The required institutional boilerplate language is provided under “What other things should you know about this research study?”

Reading Level and Spell Checking:
- Your completed version of the informed consent document should be spell checked and proofread before being submitted.
- Investigators are expected to write consent forms in simple language. The preferred reading level is 8th grade. Please be aware of the educational level of your selected study population in the country where you are working. In some populations, the reading level of the consent form may need to be lower than an 8th grade level.
- Please use the Spelling and Grammar feature of Microsoft Word or Word Perfect to check the reading level of the text of the document that you write (instructions for Microsoft Word are on pages 5 and 6 of this document).
- The standard required institutional boilerplate language under “How will your privacy be protected?” and “What other things should you know about this research study?” does not have to be checked.

Contact Information for PI or Other Study Team Members:
- Include local contact name, address, telephone number and fax number (if available) for reporting injury and for questions about the study. Make sure that the contact information inserted into the consent form is current and accurate.

Signature Lines:
- The signature page of the informed consent document must include applicable signature lines for your study.
- Include time and date of signature.

DELETE SIGNATURE LINES THAT ARE NOT REQUIRED FOR YOUR STUDY.

Approved Consent Forms: Only the approved consent form with the JHM IRB approval on the signature page or the JHM IRB Logo (for eIRB protocols) may be used to consent participants for research studies.

Questions or suggestions regarding the template should be sent to the JHM IRB office e-mail address (jhmirb@jhmi.edu).
FOR RESEARCH THAT INCLUDES CREATION OF CELL LINES OR PLURIPOTENT CELLS

FOLLOW INSTRUCTIONS BELOW AND/OR GO TO THE HUMAN PLURIPOTENT STEM CELL RESEARCH INFORMED CONSENT TEMPLATE ON THE JHM IRB WEBSITE FOR INFORMATION REQUIRED IN THE CONSENT FORM.

Section 2: Why is this research being done?

Your tissue sample may be used to create a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

- **If cell lines will be created, include the following:**

We may use the cells taken from your [specify source of cells, e.g. skin] to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including [specify type of cells, e.g. cardiac, muscle, etc.] cells. Your cells might be used in research involving genetic alteration of the cells.

- **If iPS cells will be created, include the following:**

Your cells will (if known)/might (if unknown) be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

**What you should know about the cell lines that will be derived in the course of this study?**

- The cell lines created will be similar or identical to you genetically.
- The cell lines may be kept indefinitely.
- There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.
- The cell lines may be shared with researchers both inside and outside of Johns Hopkins, including our commercial partners.
- The cell lines may be used to develop treatments for a variety of diseases and conditions.

Section 3: What will happen if you join this study?

Describe how the human biological materials will or might involve: (i) the introduction of the cells into humans; (ii) the introduction of the cells into the central nervous system of non-human primates; (iii) the introduction of the cells into non-human animals and there is significant possibility of the cells giving rise to gametes; or (iv) the creation of gametes or embryos.

Describe (i) whether the donated material will be coded or de-identified prior to research use; (ii) if the donors’ identities are retained (even if coded), whether donors can elect to be contacted to receive information through studies of the cell lines, (iii) that restricted and/or directed donation (e.g., to individuals or groups) are/is not permitted.
Common Consent Form Errors

- Do not use “treatment” or “therapy” to describe an investigational drug, device or procedure. For investigational drugs use words like, “study drug” or “study product.” For an investigational device, use words like “study device” or “study product.” For an investigational procedure, use “study procedure” or “research procedure.”

- For investigational drugs or devices, state they are investigational and describe that term (e.g., the word "investigational" means the study drug is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies. Be consistent in using “investigational” throughout the consent form. **Do not describe investigational drugs, devices or procedures as “new.”** The word "medication" or "medicine" should only be used if the drug is commercially available for that particular condition.

- Do not use the term "treatment” or “therapy” if one of the study arms will use a placebo. Clarify for the participant by using “study drug or placebo,” or “study product,” or “study substance.” Do not refer to a placebo as medicine or medication.

- Use "study doctor" (more understandable to a lay person) instead of “principal investigator.”

- Use "research study," instead of "trial."

- Use the word "participant" in the consent form instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to his/her entering the study.

- Do not use the word “invite” (for example, “You are invited to participate in a research study.”) Instead use, “You are being asked to participate in a research study because (insert condition here).”

- When describing randomization for 2 groups use, “like the flip of a coin,” for more than 2 groups, use "like drawing numbers from a hat."

- Do not use e.g. or etc., use instead, "for example," "so forth."

- Spell out acronyms when first used.

- Do not use all capital letters (CAPS) or bold items unnecessarily.

- Use initial lines or check boxes for optional portions of the study (e.g., asking permission to store samples for future research).

- For double-blind studies, include a statement that the blind can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out to what study group you are assigned.”

1. Open the Microsoft Word document for which you would like to assess readability.

2. From the top tool bar, select “Tools.” Then, from the drop-down menu, select “Options.” A box opens. Click the Spelling and Grammar tab in this box. Make sure that the last check box, titled “Show readability statistics” is selected.

3. Highlight/Select the text which you would like to assess. For consent form purposes, assess the study-related text leaving out any University boilerplate and HIPAA language.

4. Unless you know that your Microsoft Word is set for English (U.S.), then you should select “Tools” from the top tool bar. Then, from the menu that drops down, select “Language”, then select “Set Language.”

5. A dialog box will appear. Use the list provided in this box to assure that the appropriate language is highlighted. Usually, this is “English (U.S.)”. Occasionally, studies are targeting a population using another language, or another type of English, such as U.K., Singapore, etc.

6. Once you have selected a language, make sure that the option within this box that reads, “Do not check spelling or grammar” is unchecked.

7. Next, click the “OK” button at the bottom of this dialog box.

8. Now, from the top tool bar, select “Tools.” Then, from the menu that drops down, select “Spelling and Grammar,” or select the “ABC” icon from your toolbar.

9. Microsoft Word will start guiding you through the Spelling and Grammar function. Use this chance to correct spelling/grammar errors that Word may have identified. (Use discretion - This function is not fool proof!)

10. Once Spelling and Grammar are complete, a dialog box will appear asking if you would like to continue checking the remainder of the document. Click “No.”

11. Once you click “No,” a box containing the readability statistics for the selected text will open.

12. The Flesch-Kincaid Grade Level is the last number listed under the Readability section in the dialog box.

13. Click “OK” to exit Readability Statistics and to continue using this Word document.
Assessing Flesch-Kincaid Readability
Using Microsoft Word 2007

1. Open the Microsoft Word document for which you would like to assess readability.

2. Select “Office” Logo in the upper-left hand corner. Then, click on the “Word Options” Box. A box opens. Click on “Proofing” ‘tab’ on the left hand side of this box. Make sure that check box, titled “Show readability statistics” is selected under “When correcting spelling and grammar in Word” header.

3. Highlight/Select the text which you would like to assess. For consent form purposes, assess the study-related text leaving out any University boilerplate and HIPAA language.

4. Unless you know that your Microsoft Word is set for English (U.S.), then you should select “Review” on the top ”Ribbon”. Then, select “Set Language” in the ”Proofing” group.

5. A dialog box will appear. Use the list provided in this box to assure that the appropriate language is highlighted. Usually, this is ”English (U.S.)”. Occasionally, studies are targeting a population using another language, or another type of English, such as U.K., Singapore, etc.

6. Once you have selected a language, make sure that the option within this box that reads, “Do not check spelling or grammar” is unchecked.

7. Next, click the “Ok” button at the bottom of this dialog box.


9. Microsoft Word will start guiding you through the Spelling and Grammar function. Use this chance to correct spelling/grammar errors that Word may have identified. (Use discretion. This function is not fool proof!)

10. Once Spelling and Grammar are complete, a dialog box will appear asking if you would like to continue checking the remainder of the document. Click “No.”

11. Once you click “No”, a box containing the readability statistics for the selected text will open.

12. The Flesch-Kincaid Grade Level is the last number listed under the Readability section in the dialog box.

13. Click “Ok” to exit Readability Statistics and to continue using this Word document.
# Review of Required and Additional Elements

This checklist is provided to help you in the preparation of the consent form. Do not submit this checklist with the consent form.

## Verify that the informed consent document contains each of the eight required elements (45 CFR 46.116)

<table>
<thead>
<tr>
<th>Item #</th>
<th>ITEMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>a statement that the study involves research, and</td>
</tr>
<tr>
<td>1b</td>
<td>an explanation of the purposes of the research, and</td>
</tr>
<tr>
<td>1c</td>
<td>the expected duration of the participant’s participation, and</td>
</tr>
<tr>
<td>1d</td>
<td>a description of the procedures to be followed, and</td>
</tr>
<tr>
<td>1e</td>
<td>identification of any procedures which are experimental;</td>
</tr>
<tr>
<td>2</td>
<td>a description of any reasonably foreseeable risks or discomforts to the participant;</td>
</tr>
<tr>
<td>3</td>
<td>a description of any benefits to the participant or to others which may reasonably be expected from the research</td>
</tr>
<tr>
<td>4</td>
<td>a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;</td>
</tr>
<tr>
<td>5a</td>
<td>a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and</td>
</tr>
<tr>
<td>5b</td>
<td>if the research is subject to FDA regulation, a statement that notes the possibility that FDA may inspect the records</td>
</tr>
<tr>
<td>6a</td>
<td>for research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs and,</td>
</tr>
<tr>
<td>6b</td>
<td>if so, what they consist of, or where further information may be obtained;</td>
</tr>
<tr>
<td>7a</td>
<td>an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and</td>
</tr>
<tr>
<td>7b</td>
<td>whom to contact in the event of a research-related injury to the participant;</td>
</tr>
<tr>
<td>8a</td>
<td>a statement that participation is voluntary, and</td>
</tr>
<tr>
<td>8b</td>
<td>a statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and</td>
</tr>
<tr>
<td>8c</td>
<td>a statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.</td>
</tr>
</tbody>
</table>

## When appropriate, which of the following additional elements of information are provided in the consent form?

<table>
<thead>
<tr>
<th>Item #</th>
<th>ITEMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable; and</td>
</tr>
<tr>
<td>1b</td>
<td>if the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable;</td>
</tr>
<tr>
<td>2</td>
<td>anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent;</td>
</tr>
<tr>
<td>3</td>
<td>any additional costs to the participant that may result from participation in the research;</td>
</tr>
<tr>
<td>4</td>
<td>If this is a clinical trial, a statement that the research will be entered into the clinicaltrials.gov website;</td>
</tr>
<tr>
<td>5a</td>
<td>the consequences of a participant’s decision to withdraw from the research; and</td>
</tr>
<tr>
<td>5b</td>
<td>procedures for orderly termination of participation by the participant;</td>
</tr>
<tr>
<td>6</td>
<td>a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant</td>
</tr>
<tr>
<td>7</td>
<td>The approximate number of participants involved in the study.</td>
</tr>
</tbody>
</table>
Site of Research:
King Khaled Eye Specialist Hospital
Saudi Arabia

RESEARCH PARTICIPANT INFORMED CONSENT
AND PRIVACY AUTHORIZATION FORM

Protocol Title: 

Application No.:  

Sponsor:  

Principal Investigator:  

1. What you should know about this study:
   • You are being asked to join a research study.
   • The research study is a collaboration between the Johns Hopkins University School of Medicine in
     Baltimore, Maryland (USA) and the King Khaled Eye Specialist Hospital in Saudi Arabia.
   • This consent form explains the research study and your part in the study.
   • Please read it carefully and take as much time as you need.
   • Please ask questions at any time about anything you do not understand.
   • You are a volunteer. If you join the study, you can change your mind later. You can decide not to
     take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit
     the study.
   • During the study, we will tell you if we learn any new information that might affect whether you
     wish to continue to be in the study.
   • Ask your study doctor or the study team to explain any words or information in this informed
     consent that you do not understand.
   • For clinical trials: A description of this clinical trial will be available at www.ClinicalTrials.gov, as
     required by U.S. Law. This Web site will not include information that can identify you. At most, the
     Web site will include a summary of the results. You can search the Web site at any time.
   • If children and adults can join this study, the word “you” in this consent form will refer to both you
     and your child.

If this study does not involve children, you may delete this bullet. If the study involves only
children, then the term “your child” should be used in the consent form.

   • The person being asked to be in this research study may not be able to give consent to be in this
     study. You are therefore being asked to give permission for this person to be in the study as his/her
     decision maker.

Include this bullet if cognitively impaired adults will be in the study:
2. Why is this research being done?

Start with an introductory sentence describing the primary purpose of the research as stated in the protocol:

This research is being done to....

- State what the study is designed to discover or establish. If this is a treatment study, describe the nature of the experimental design and how it differs from standard clinical care (including, for example: projected differences in morbidity and mortality rates, consequent medication differences that might affect participants, what factors the PI considered in choosing the experimental design, etc.) Identify any procedures that are experimental.

- If cell lines may be created from tissue samples or iPS cells are used in this research, include the information on page 3 of this template.

- If you are using a drug or device that is investigational and is not approved by the United States Food and Drug Administration, state that the drug, combination of drugs, device, etc. are investigational and include the following language (if the drug or device is approved outside of the United States, that information must also be included):

The use of “X” (study drug or device name) in this research study is investigational. The word “investigational” means that “X” is not approved for marketing by the United States Food and Drug Administration (FDA). The FDA is allowing the use of “X” in this study.
“X” (drug or device name) is approved by the United States Food and Drug Administration (FDA) for the treatment of ___ (include disease name). It is not approved for use in ___ (disease name). The FDA is allowing the use of _“X” in this research study.

If you are using an FDA approved drug or device, but not for an FDA-approved purpose, include the following:

If the FDA may approve the study drug while the research study is in process, include information on whether participants will be responsible for paying for the study drug if it is approved.

3. What will happen if you join this study?

Start with the statement:

- Describe the procedures chronologically using lay language, short sentences, and short paragraphs.
- Volume measurements (e.g., blood draws) should be provided in measurements understandable to local population (e.g., ml).
- Distinguish which procedures are part of the study and which are standard clinical treatments.
- Clarify any change in participant’s care as s/he shifts from standard clinical care to the study intervention.
- Define and explain all medical and scientific terms in ordinary language.
- Specify the assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of procedures, etc.
- For clinical trials, explain if any treatment will be available to participants after study completion. If a placebo arm is included in the trial, explain whether participants will be able to receive the study drug/intervention after study completion.

For research involving randomization, specify the randomization procedure. For two groups use language like “flipping a coin.” If your research includes more than two groups use “like drawing numbers from a hat.”
4. **What are the risks or discomforts of the study?**

Identify each intervention with a subheading and then describe any reasonable risks, discomforts, inconveniences, and how these will be managed. Each medication used must be listed. Within subheadings, consider the use of bulleted items.

**In a treatment study, describe the risks associated with joining the study as compared with the risks associated with continuing standard clinical care.**

List risks in order of relative probability (e.g., “likely,” “less likely” or “unlikely,” and “rare but serious”). Always include risk of death in studies that involve serious underlying disease.

**All drugs that are mandated (i.e., no substitutions permitted) by the protocol, even those that are standard of care, must be included in the procedures section, and the risks that are listed on their package inserts should be described in this section.**

In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk for the loss of confidentiality of sensitive information.
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

There may be side effects and discomforts that are not yet known.

5. **Are there risks related to pregnancy?**

   - Insert this heading and section if applicable.
   - Describe foreseeable risks to a fetus.
   - Describe any required pregnancy testing and actions that may be taken if the participant or a participant’s partner becomes pregnant. This should also include the requirement of adequate birth control measures for women capable of having children and for men (when appropriate to a study).
   - If the research involves pregnant women or women capable of having children, and the risk profile of the research procedures on an embryo or fetus are not well known, end with the statement:

This research may hurt an embryo or fetus in ways we do not currently know.

6. **Are there benefits to being in the study?**

State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there are no direct benefits, state:

If you take part in this study, you may help others in the future.

Do NOT include financial rewards for participation in the study. Any payment to participants should be included in the “Will you be paid if you join this study” section. Results of tests given to participants are not considered a benefit. If results will be provided this should be explained in “What will happen if you join this study?”
7. **What are your options if you do not want to be in the study?**

   - **Describe any alternatives that should be considered before deciding whether or not to be in the study. If applicable, explain why these procedures are being withheld. If there are no alternatives, state that an alternative is to not take part in the study.**
   - **In a treatment study, describe the option of continuing with standard clinical care and whether clinical care could include the study intervention proposed.**
   - **If the prospective participants are suffering from a terminal illness, and there are no alternative treatments available, you should say so, but you might include some palliative care language.**
   - **If the prospective participants have a chronic, progressive disorder for which no treatment has been demonstrated to be safe and effective, say that as well.**
   - **Avoid suggesting that participation in the research is the only way to obtain medical care and attention.**

   **If other treatments are available to the participant, include the following:**

   If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments include (describe treatments)

   **End with the statement:**

   You do not have to join this study. If you do not join, your care at Johns Hopkins and the King Khaled Eye Specialist Hospital will not be affected

8. **Will it cost you anything to be in this study?**

9. **Will you be paid if you join this study?**

   - **Payments should be described in terms of local currency. Include a description of payment in relative terms (i.e., payment equates to a day’s work, hourly salary, or another local reference)**
   - **State whether the participant will be paid or offered other types of rewards (e.g., coupons, gift certificates). If not, state “No.”**
   - **List rates of payment or other financial rewards (transportation, babysitting, etc.).**
   - **List method and timing of payment, and provisions for partial payment if a participant leaves early.**

10. **Can you leave the study early?**

    **If appropriate to the study, add some or all of the following statements:**

    - You can agree to be in the study now and change your mind later.
    - If you wish to stop, please tell us right away.
    - Leaving this study early will not stop you from getting regular medical care.
    - If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.
11. **Why might we take you out of the study early?**

   *If gradual withdrawal will be required for safety considerations, explain this and any unique procedure(s) required for timely and safe withdrawal.*

   *If appropriate to the study, add some or all of the following statements:*

   You may be taken out of the study if:
   - Staying in the study would be harmful.
   - You need treatment not allowed in the study.
   - You fail to follow instructions.
   - You become pregnant.
   - The study is cancelled.
   - There may be other reasons to take you out of the study that we do not know at this time.

12. **How will your privacy be protected?**

   *If sponsor would like to add further information in this section, you may do so and the JHM IRB will decide if the language is acceptable.*

   Some of your health information collected in this study will be sent to the United States. The U.S. has privacy laws that will protect your information and your identity.

   If you want to be in the study, you must agree to let us use and send details about you and your health as part of this study. *(Optional section: This study uses (a drug or drugs; or a device or devices). The U.S. Food and Drug Administration (FDA) may need to see your health information when it is sent to the U.S.)*

   If you join the study, you can decide later that you want to leave the study and you do not want to have your health information sent to the U.S. If you decide to leave the study, no more information about you will be collected. However, we will not be able to take back the health information that has already been sent to the U.S. To leave the study, tell the principal investigator.

13. **Will the study require any of your other health care providers to share your health information with the researchers of this study?**

   *Insert this heading and section if applicable.*

   As a part of this study, the researchers may ask to see your health care records from your other health care providers.

   - Optional: You will be asked to give us a list of other health care providers that you use.
14. What does a conflict of interest mean to you as a participant in this study?

A conflict of interest occurs when a researcher, Johns Hopkins or King Khaled Eye Specialist Hospital has/had a financial or other interest that might affect the researcher’s judgment when conducting a research study. In some situations, the results of a study might lead to a financial gain for the investigator(s) and/or Johns Hopkins.

One or more of the investigators working in this research study has/had a financial conflict of interest in connection with the study.

If you have any questions about this conflict of interest, please talk to insert name and telephone number of a non-conflicted individual at Johns Hopkins and name and telephone number of Director of Research at King Khaled Eye Specialist Hospital. These people do not have a conflict of interest related to the study. You can also call the Office of Policy Coordination (00-1-410-516-5560) at Johns Hopkins for more information. The Office of Policy Coordination manages conflicts of interest.

15. What treatment costs will be paid if you are injured in this study?

If you have suffered a study-related injury as a participant in this study, you should contact insert name of local contact at insert phone number.

16. What other things should you know about this research study?

a. What is an Institutional Review Board (IRB) and how does it protect you?

IRBs review human research studies. They protect the rights and welfare of people taking part in research studies

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

If you have questions about your rights as a participant or if you think you have not been treated fairly, you may contact the King Khaled Eye Specialist Hospital IRB at insert address, telephone
b. What do you do if you have questions about the study?
Call insert name of local contact at insert address, telephone and fax numbers who will be able to answer any questions about this study. If you would like to speak to the principal investigator at Johns Hopkins in the United States, call Dr. insert PI’s name at insert telephone number.

b. What should you do if you are injured or ill as a result of being in this study?
Call insert name of local physician at phone or pager number available 24 hours, if you have an urgent medical problem related to your taking part in this study.

If you insert a pager number, include the following instructions: After the tone, enter the phone number where you can be called, press the # key, and hang up.

Call insert name of local physician at insert telephone number, if you think you are injured or ill because of this study.

c. What happens to Data, Tissue, Blood and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:
- You will not own the data, tissue, blood and specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research will study your data and the tissue, blood or other specimens collected from you.
- Scientists may only use data, tissue, blood and specimens that identify you for future research with your consent or IRB approval.
- If data, tissue, blood or other specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the investigators working on this study.
- You will not receive any financial benefit from the creation, use or sale of that product or idea.

d. Assent Statement

Insert this statement if the study includes children, except when (a) the child is incapable of understanding the explanation; or, (b) the study intervention offers the prospect of direct benefit to the child that is only available through research.

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.
18. **What is a Genome-Wide Association Study?**

Genome-wide association studies (GWAS) look at the genetic differences that exist in the entire human genome (the complete set of human genes) and the association between these differences and health conditions.

As part of this study, we will be collecting information about your health and your individual genes. This information will be sent to the National Institutes of Health (NIH) GWAS database called dbGAP (Database of Genotypes and Phenotypes).

The aim of collecting this information is to look for genetic connections that:
- may make people more likely to get a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity)
- may affect the progress of a certain disease or condition
- may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We will remove direct identifiers and code your information before sending it to the NIH. NIH will never get this code or the identifiers we have removed.

Johns Hopkins will not know what types of research will be done with the data that are sent to the database.

GWAS data will be shared with other researchers world-wide through the dbGaP Database. This database is kept at the National Center for Biotechnology Information (NCBI) at the NIH.

Researchers must apply to NIH to use the dbGaP database. Special review committees will look at these applications to decide whether or not to share the data. Researchers must agree to keep data safe and use the data only for the purpose approved by the NIH.

**What are the risks of data being stored for GWAS?**

There may be risks to your privacy and the privacy of your relatives from storing your information in a GWAS database.

Although we believe that the NIH privacy measures make this unlikely, there is a risk that your identity could become re-connected with your genetic and health information.

If this happened -
- Information could be revealed that could lead to denial of employment or insurance for you or a relative, or
- Law enforcement agencies might be able to demand information about you in connection with an investigation.

**Are there benefits to being in a GWAS study?**

There is no direct benefit to you from GWAS research. The information from your data may lead to a better understanding of how genes affect health. This may help other people in the future.
19. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

<table>
<thead>
<tr>
<th>Signature of Participant</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Signature of Person Obtaining Consent</th>
<th>Date/Time</th>
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<tbody>
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<td></td>
<td></td>
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</tbody>
</table>

Add any of the following that are applicable for this study and delete any that do not apply

<table>
<thead>
<tr>
<th>Signature of Legally Authorized Representative (LAR) for ADULTS NOT CAPABLE of GIVING CONSENT</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker)</th>
<th>Date/Time</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Signature of Parent</th>
<th>Date/Time</th>
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<table>
<thead>
<tr>
<th>Signature of Legally Authorized Representative (LAR) for CHILD RESEARCH PARTICIPANT</th>
<th>Date/Time</th>
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<table>
<thead>
<tr>
<th>Relationship of LAR to Child Research Participant (indicate why LAR is authorized to act as surrogate health care decision-maker for child research participant, for example, Legal Guardian, court-ordered representative)</th>
<th>Date/Time</th>
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</table>

<table>
<thead>
<tr>
<th>Signature of Parent #2 (required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)</th>
<th>Date/Time</th>
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<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Signature of Child Participant (optional unless IRB required)</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
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</table>

<table>
<thead>
<tr>
<th>Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)</th>
<th>Date/Time</th>
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NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD.

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED FOR CONSENTING RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO CONSENT RESEARCH PARTICIPANTS.
RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: 

Application No.: 

Sponsor:  

Principal Investigator: Include name, address, phone and fax information

1. What you should know about this study: 
   • You are being asked to join a research study. 
   • The research study is a collaboration between the Johns Hopkins University School of Medicine in Baltimore, Maryland (USA) and the King Khaled Eye Specialist Hospital in Saudi Arabia. 
   • This consent form explains the research study and your part in the study. 
   • Please read it carefully and take as much time as you need. 
   • Please ask questions at any time about anything you do not understand. 
   • You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study. 
   • During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study. 
   • Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand. 
   • For clinical trials: A description of this clinical trial will be available at www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.
   • If children and adults can join this study, the word “you” in this consent form will refer to both you and your child.
   • The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

If this study does not involve children, you may delete this bullet. If the study involves only children, then use the “Parental” Informed Consent Template posted on the JHM IRB website.

Include this bullet if cognitively impaired adults will be in the study:
2. **Why is this research being done?**
   This research is being done to...

   People with _____ may join.

3. **What will happen if you join this study?**
   If you agree to be in this study, we will ask you to do the following things:

   **How long will you be in the study?**
   You will be in this study for

4. **What are the risks or discomforts of the study?**

5. **Are there risks related to pregnancy?**

6. **Are there benefits to being in the study?**

7. **What are your options if you do not want to be in the study?**
   You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. **Will it cost you anything to be in this study?**

Include this bullet if results from clinical tests will be included in the medical record:

- A statement will be added to your medical record that you are in this research study. Results from any clinical tests you have will be included in your medical record. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.

Include this for a blinded study or a study where medical information will not be available to participants until the study is completed:

- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

If this study will include submission of data to the Genome-Wide Association Study (GWAS) data repository, include the following language:

- As part of this study, we will collect genetic information about you and the resulting data will be sent to the National Institutes of Health (NIH) Genome-Wide Association Study (GWAS) repository. Please see the last page of this consent form for information about GWAS and your data.
9. Will you be paid if you join this study?

10. Can you leave the study early?

11. Why might we take you out of the study early?

12. How will your privacy be protected?

Some of your health information collected in this study will be sent to the United States. The U.S. has privacy laws that will protect your information and your identity.

If you want to be in the study, you must agree to let us use and send details about you and your health as part of this study.  (Optional section:  This study uses (a drug or drugs; or a device or devices).  The U.S. Food and Drug Administration (FDA) may need to see your health information when it is sent to the U.S.)

If you join the study, you can decide later that you want to leave the study and you do not want to have your health information sent to the U.S.  If you decide to leave the study, no more information about you will be collected. However, we will not be able to take back the health information that has already been sent to the U.S.  To leave the study, tell the principal investigator.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

14. What does a conflict of interest mean to you as a participant in this study?

15. What treatment costs will be paid if you are injured in this study?

16. What other things should you know about this research study?

   a. What is an Institutional Review Board (IRB) and how does it protect you?

   IRBs review human research studies. They protect the rights and welfare of people taking part in research studies

   The Johns Hopkins Medicine IRB is made up of:
   - Doctors
   - Nurses
b. What do you do if you have questions about the study?

Call **insert name of local contact** at **insert address, telephone and fax numbers** who will be able to answer any questions about this study. If you would like to speak to the principal investigator at Johns Hopkins in the United States, call Dr. **insert PI’s name** at **insert telephone number**.

c. What should you do if you are injured or ill as a result of being in this study?

Call **insert name of local physician** at **phone or pager number available 24 hours**, if you have an urgent medical problem related to your taking part in this study.

*If you insert a pager number, include the following instructions:* After the tone, enter the phone number where you can be called, press the # key, and hang up.

Call **insert name of local physician** at **insert telephone number**, if you think you are injured or ill because of this study.

d. What happens to Data, Tissue, Blood and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, tissue, blood and specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research will study your data and the tissue, blood or other specimens collected from you.
- Scientists may only use data, tissue, blood and specimens that identify you for future research with your consent or IRB approval.
- If data, tissue, blood or other specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the investigators working on this study.
- You will not receive any financial benefit from the creation, use or sale of that product or idea.

If your study does not include tissue, blood and specimens, you may delete these words from the heading and text.
17. **Assent Statement**

*Delete this heading if not applicable.*

18. **What is a Genome-Wide Association Study?**

*Delete this heading if not applicable.*
19. **What does your signature on this consent form mean?**

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

<table>
<thead>
<tr>
<th>Signature of Participant</th>
<th>Date/Time</th>
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<tr>
<th>Signature of Person Obtaining Consent</th>
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**Add any of the following that are applicable for this study and delete any that do not apply**

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<tr>
<td>Signature of Legally Authorized Representative (LAR) for <strong>ADULTS NOT CAPABLE of GIVING CONSENT</strong> <em>(Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)</em></td>
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<tr>
<td>Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker)</td>
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<tr>
<td>Signature of Parent</td>
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<tr>
<td>Signature of Legally Authorized Representative (LAR) for <strong>CHILD RESEARCH PARTICIPANT</strong></td>
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<td>Date/Time</td>
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<tr>
<td>Relationship of LAR to child research participant (indicate why the LAR is authorized to act as surrogate health care decision-maker for child research participant, for example, Legal Guardian, court-ordered representative)</td>
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<tr>
<td>Signature of Parent #2 (required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)</td>
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<td>Date/Time</td>
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<tr>
<td>Signature of Child Participant (optional unless IRB required)</td>
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<tr>
<td>Date/Time</td>
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<tr>
<td>Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)</td>
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<td>Date/Time</td>
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**NOTE:** A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED FOR CONSENTING RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO CONSENT RESEARCH PARTICIPANTS.**