Welcome to the first edition of the Research Department newsletter: EYERES. This quarterly newsletter was developed by the Research Dept. to provide research news to KKESH staff, regulatory updates and answer frequently asked questions relating to human subjects research. The letter will be distributed electronically four times each year and posted on the KKESH website.

In addition, to present issues relevant to human subjects’ participation in biomedical and behavioural research, EYERES will also periodically feature “guest” articles from investigators and IRB members.

Please send comments, questions or suggestions for future issues to Manuel Oliva, IRB Manager, EYERES Editor, at moliva@med.kkesh.sa.

Welcome note Dr. Al-Towerki

I congratulate the Research Department on this inaugural issue of the research newsletter. This quarterly communication will keep the medical staff informed of the activities of the research Department and update us on the research achievements of our staff and trainees.

Best wishes

Abdul-Elah Abad Al-Towerki, MD
Senior Academic Consultant
Anterior Segment: Cornea, Refractive Surgery
General Executive Director
King Khaled Eye Specialist Hospital

Welcome note Dr. Behrens

The Research Department at KKESH has undergone major, accelerated and exciting changes in the past few months under the leadership of Dr. Deepak Edward. KKESH clinician-researchers are becoming actively involved in new projects, some of them unique in the world.

EYERES newsletter is the perfect method to deploy important information for interested parties and potential collaborators within and outside the Kingdom.

I congratulate Dr. Manuel Oliva, Editor, for the brilliant initiative, and wish him and his team success in keeping EYERES as the new pathway to keep our community updated.

Ashley Behrens, M.D.
Executive Medical Director
Senior Academic Consultant and KKESH/WEI Professor of International Ophthalmology
King Khaled Eye Specialist Hospital • Riyadh • Saudi Arabia
The Wilmer Eye Institute • Johns Hopkins University • Baltimore, Maryland • United States
Human Subjects Education Requirements

All KKESH Investigators and key research personnel who participate in human subject’s research must be trained in human subject’s protection. The Collaborative IRB Training Initiative (CITI) web-based course with nine modules was selected to satisfy this requirement.

Investigators who conduct any type of clinical study should take this course online. Each module must be passed with a minimum score of 80%. Please contact research Department on how to sign up for course.

Human Subjects Research FAQs

Institutional Review Board (IRB) review of human subjects research is required to protect the rights and welfare of participants in research conducted under the auspices of the Saudi Food and Drug Administration (SFDA) and National Committee of Medical & Bioethics (NCMB). The IRB has the authority to approve, require modifications in, or disapprove all research activities as defined by national regulations (SFDA and NCMB).

The first two questions investigators and IRBs must answer are whether a proposed activity involves “research” and, if so, whether the research involves “human subjects”.

How do I know if my proposed activity involves research?

“Research” is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research is described in a protocol that includes an objective(s) and a set of procedures designed to reach that objective (i.e., systematic). In contrast, “treatment” or “professional practice” involves performing interventions designed solely to enhance the well-being of a particular individual.

“Clinical investigation” means any experiment that involves a test article (any drug, biological product, medical device, food or color additive, electronic product, or any other article regulated by SFDA) and one or more human subjects. The terms research, clinical research, clinical study, study, and clinical investigation are generally used interchangeably.

How do I know if my proposed activity involves human subjects?

SFDA regulations define “human subjects” as living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

For oversight purposes, the KKESH’s IRB has generally interpreted this definition to include all data and biological materials obtained from persons living or dead. Therefore, your research probably involves human subjects if it includes:

• Performing biomedical studies on humans or on human specimens
• Administering surveys; interviewing or observing individuals
• Audioc taping or videotaping people
• Using stored specimens collected from humans
• Reviewing existing data containing identifiable private information

Recently published papers on Pubmed by KKESH staff

Recently listed papers by KKESH staff on PubMed accessed January 20 (please let us know if your publication is not listed):


Recently approved projects

Below is a listing of the projects most recently approved for the HEC/IRB during the last three months of 2012.

<table>
<thead>
<tr>
<th>Project</th>
<th>Title</th>
<th>Principal Investigator(s)</th>
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<td>1243-R</td>
<td>Hazards of Laser Pointer on the Human Eye: Clinical Manifestations</td>
<td>Sultan Al-Zaibed</td>
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<tr>
<td>1251-R</td>
<td>The Clinical Spectrum of Sturge-Weber Syndrome at KKESH</td>
<td>Sami Al-Shabban</td>
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<tr>
<td>1256-CR</td>
<td>Spontaneous Closure of Macular Hole after Laser Pointer Injury</td>
<td>Mohammad Al-Amry</td>
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<td>1257-CH</td>
<td>Endophthalmitis: Experience from a Tertiary Eye Care Center (book: Common Eye Infections)</td>
<td>Hasaan Al-Dhibi</td>
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<td>1258-CR</td>
<td>Non-arteritic Ischemic Optic Neuropathy (NAION) in Amphetamine Drug Abuser</td>
<td>Malek Al-Robian</td>
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<td>1259-R</td>
<td>Selective Laser Trabeculoplasty Results In Kkesh, One Year Review</td>
<td>Leyla Al-Jasim</td>
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<td>1261-R</td>
<td>Common Ophthalmic Presentation of Intracranial Pathology in Children</td>
<td>Noof Al-Swatna</td>
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<td>1262-R</td>
<td>Retrospective Review of Chemotherapy for Children with Retinoblastoma</td>
<td>Mohamed Karrouni</td>
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<td>1263-F</td>
<td>International Pilot Survey of Childhood Glaucoma</td>
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<td>1264-R</td>
<td>Orbital Inflammation Gene Expression Profiling</td>
<td>Hailah Al-Hussaini Haid Al-Kutai</td>
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<td>1265-R</td>
<td>Visual and Anatomically Outcomes of Bevacizumab in Diabetic Macular Edema</td>
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<td>1268-CH</td>
<td>Full-thickness macular hole secondary x-linked juvenile retinoschisis</td>
<td>Nasef Al-Swatna Sawsan Nowailaty</td>
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<td>1272-R</td>
<td>Longitudinal changes in incidence of neovascular glaucoma at KKESS</td>
<td>Igor Kezak</td>
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