How To Apply for an IRB* (REC**) Approval? (HANDS-ON)

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Second Research Course
Undergraduate Medical Students
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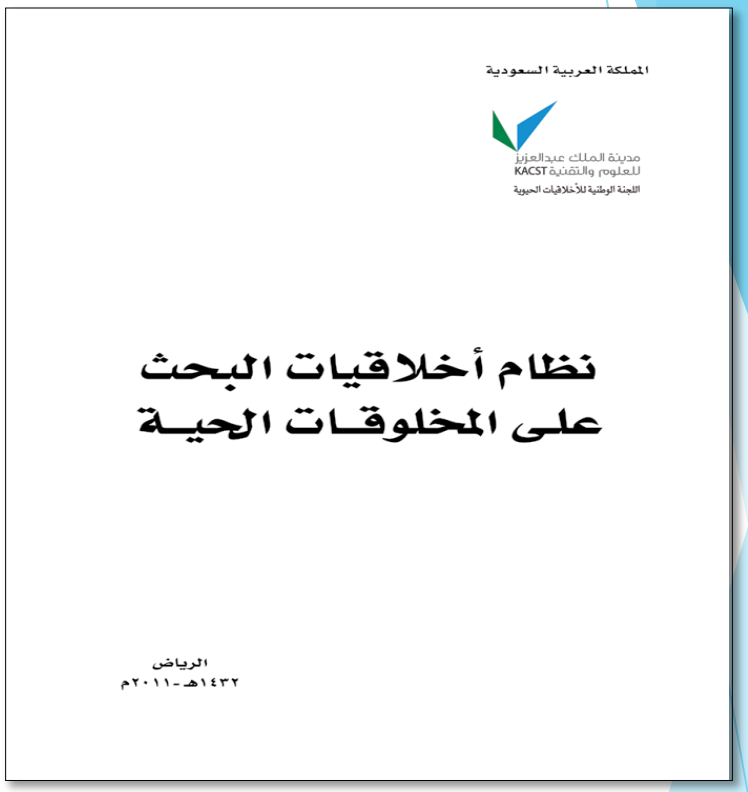
* IRB = Institution Review Board
** REC = Research Ethics Committee

برنامج لجنة أخلاقيات البحوث - جامعة الملك سعود

Session Contents

- How were the updated KSU REC Forms prepared
- Different types of Studies that need Ethical approval
- Researchers' Forms and Applications Submission
- Hands-on activities:
  - Fill a **Proposal Application for Research Involving Human Participants (Form # KSU-REC 002E)**
  - Fill a **INFORMED CONSENT FOR MEDICAL STUDIES (CLINICAL) Form # KSU-REC 006-E and Form # KSU-REC 006-A**

نظام أخلاقيات البحث على المخلوقات الحية



اللائحة التنفيذية الصادرة من مدينة الملك عبد العزيز للعلوم والتقنية

اللائحة الداخلية للجنة المحلية الدائمة واللجان الفرعية لأخلاقيات البحث على المخلوقات الحية

Preparation of the KSU REC FORMS

Approach taken:

1. The search on local and international IRBs.
2. Reviewing the guidelines (KACST, ..etc)
3. Categorizing the forms (Medical, Scientific, Human studies, Plants)
4. Preparing the infrastructure for a website: KSU IRB.

(http://dsrs.ksu.edu.sa/ar/comm_Policies)

النماذج المطلوبة لإستيفاء التقديم تعتمد على طبيعة البحث المقدم

1-التجارب السريرية

نماذج يلزم استيفاؤها:
- نموذج قائمة تدقيق.
- نموذج طلب التقديم على المقترح البحثي لبحث متضمن مشاركة بشرية.
- المقترح البحثي.
- نموذج قائمة التدقيق الموافقة بعد التبصير.
- إقرار بالموافقة على المشاركة في بحث للتجارب السريرية.
- تقرير عن سير البحث للتجارب السريرية.
- التقرير النهائي (استكمال الدراسة أو إنهائها).

نماذج يتم استيفاؤها إذا تطلب البحث :
- نموذج إعفاء في حالة الطوارئ من الموافقة على المشاركة في التجارب السريرية.
- نموذج استخدام الخلايا الجذعية، بويضات . ملقحة ، أمشاج ، وأجنة.
- نموذج استخدام الأجهزة.
- نموذج استخدام الأدوية و/أو المنتجات البيولوجية.
- طلب تعديل مشروع تم اعتماده.
- الأحداث السلبية، الأحداث السلبية الخطيرة والغير متوقعة.
- طلب إرسال عينات حيوية (بشرية) لخارج المملكة العربية السعودية.
- طلب إعادة الموافقة على بحث تم اعتماده مسبقاً.

2- الدراسات الطبية/العلمية (بشرية)

نماذج يلزم استيفاؤها:
- نموذج قائمة تدقيق.
- نموذج طلب التقديم على المقترح البحثي لبحث متضمن مشاركة بشرية.
- المقترح البحثي.
- نموذج قائمة التدقيق الموافقة بعد التبصير.
- نموذج إقرار بالموافقة على المشاركة في بحث طبي أو علمي.
- تقرير عن سير البحث لبحث طبي/ علمي/ إنساني/نباتي.
- التقرير النهائي (استكمال الدراسة أو إنهائها).

نماذج يتم استيفاؤها إذا تطلب البحث :
- نموذج استخدام حيوانات التجارب.
- نموذج استخدام الخلايا الجذعية، بويضات . ملقحة ، أمشاج ، وأجنة.
- نموذج استخدام الأجهزة.
- نموذج استخدام الأدوية و/أو المنتجات البيولوجية.
- طلب تعديل مشروع تم اعتماده.
- الأحداث السلبية، الأحداث السلبية الخطيرة والغير متوقعة.
- طلب إرسال عينات حيوية (بشرية) لخارج المملكة العربية السعودية.
- طلب إعادة الموافقة على بحث تم اعتماده مسبقاً.

3- الدراسات الحيوانية

نماذج يلزم استيفاؤها:
- نموذج قائمة تدقيق.
- المقترح البحثي.
- نموذج استخدام حيوانات التجارب.
- تقرير عن سير البحث لبحث طبي/ علمي/ إنساني/نباتي.
- التقرير النهائي (استكمال الدراسة أو إنهائها).

نماذج يتم استيفاؤها إذا تطلب البحث :
- نموذج طلب التقديم على المقترح البحثي لبحث متضمن مشاركة بشرية.
- نموذج قائمة التدقيق الموافقة بعد التبصير.
- نموذج استخدام الخلايا الجذعية، بويضات ملقحة ، أمشاج ، وأجنة.
- نموذج استخدام الأجهزة.
- نموذج استخدام الأدوية و/أو المنتجات البيولوجية.
- طلب تعديل مشروع تم اعتماده.
- الأحداث السلبية، الأحداث السلبية الخطيرة والغير متوقعة.
- طلب إعادة الموافقة على بحث تم اعتماده مسبقاً.

4- الدراسات الإنسانية

نماذج يلزم استيفاؤها:
- نموذج قائمة تدقيق.
- نموذج طلب التقديم على المقترح البحثي لكليات الدراسات الإنسانية.
- المقترح البحثي لكليات الدراسات الإنسانية.
- نموذج قائمة التدقيق الموافقة بعد التبصير.
- إقرار بالموافقة على المشاركة في بحث للدراسات الإنسانية.
- تقرير عن سير البحث لبحث طبي/ علمي/ إنساني/نباتي.
- التقرير النهائي (استكمال الدراسة أو إنهائها).

نماذج يتم استيفاؤها إذا تطلب البحث :
- طلب تعديل مشروع تم اعتماده.
- طلب إعادة الموافقة على بحث تم اعتماده مسبقاً.

5- الدراسات النباتية

نماذج يلزم استيفاؤها:
- نموذج قائمة تدقيق.
- نموذج طلب التقديم على مقترح بحثي للنباتات.
- المقترح البحثي.
- تقرير عن سير البحث لبحث طبي/ علمي/ إنساني/نباتي.
- التقرير النهائي (استكمال الدراسة أو إنهائها).

نماذج يتم استيفاؤها إذا تطلب البحث :
- نموذج استخدام الخلايا الجذعية، بويضات ملقحة ، أمشاج ، وأجنة.
- نموذج استخدام الأجهزة.
- نموذج استخدام الأدوية و/أو المنتجات البيولوجية.
- طلب تعديل مشروع تم اعتماده.
- طلب إعادة الموافقة على بحث تم اعتماده مسبقاً.

Study Category, نوعية الدراسة	Description
A Clinical Trials: التجارب السريرية	Experiments conducted on human volunteers to examine safety and effectiveness of a new medication or medical device. By taking part in clinical trials, participants can not only play a more active role in their own health care, but they can also access new treatments and help others by contributing to medical research.
Medical/Scientific Research (Human): الدراسات الطبية/العلمية (بشرية)	A Research conducted on human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects, or with samples obtained from them. It is a research that directly involves a particular person or group of people; or that uses materials from humans, such as their behavior or samples of their tissue.
Scientific Research(Animal) : الدراسات الحيوانية	A research that directly involves a particular animal or group of animals, or that uses materials from animals, such as their behavior or samples of their tissue
Humanities Colleges Studies: الدراسات الإنسانية	Basic research on the relations among cultural processes, attitudes, health behaviors, and outcomes, can lead to more precise measurement on social-behavioral mechanisms of culture, and can provide reliable and valid grounding for measures across future disease-specific and/or target-population-specific investigations.
Plants Studies: الدراسات النباتية	A research that directly involves a particular plant or group of plants, or that uses tissues obtained from plants.

Researchers' Forms and Applications Submission

Instructions for Applicants
تعليمات للمتقدمين

S. No.	Forms	Clinical Trials	Medical/Scientific (Human)	Scientific (Animal)	Humanities Colleges Studies	Plants Studies
1	Application Checklist نموذج قائمة تدقيق	KSU-REC001-E	KSU-REC001-E	KSU-REC001-E	KSU-REC001-E KSU-REC001-A	KSU-REC001-E
2	Proposal Application for Research Involving Human Participants نموذج التقديم للبحث الذي ينطوي على مشاركة بشرية	KSU-REC002-E	KSU-REC002-E	KSU-REC002-E (if applicable)	×	×
2-B	Proposal Application for Research Involving Plants Only نموذج التقديم لبحث الدراسات النباتية	×	×	KSU-REC002B-E (if applicable)	×	KSU-REC002B-E
2-C	Proposal Application for Humanities Colleges Studies نموذج التقديم لبحث دراسات الكليات الإنسانية	×	×	×	KSU-REC002C-E KSU-REC002C-A	×
3	Research Proposal المقترح البحثي	KSU-REC003-E	KSU-REC003-E	KSU-REC003-E	×	KSU-REC003-E
3-B	Research Proposal for Humanities Colleges Studies المقترح البحثي لدراسات الكليات الإنسانية	×	×	×	KSU-REC003B-E KSU-REC003B-A	×
4	Informed Consent Checklist نموذج قائمة التدقيق للموافقة بعد التبصير	KSU-REC004-E	KSU-REC004-E	KSU-REC004-E	KSU-REC004-E	×
5	Informed Consent For A Clinical Trial إقرار بالموافقة على المشاركة في التجارب الإكلينيكية	KSU-REC005-E KSU-REC005-A	×	×	×	×

6	Informed Consent For A Medical/Scientific Research إقرار بالموافقة على المشاركة في بحث طبي / علمي	×	KSU-REC006-E KSU-REC006-A	×	×	×
6-B	Informed Consent For A Humanity Study إقرار بالموافقة على المشاركة في بحث لدراسات الكليات الإنسانية	×	×	×	KSU-REC006B-E KSU-REC006B-A	×
7	Emergency Exemption From Consent Form for Clinical Trials	KSU-REC007-E (if needed)	×	×	×	×
8	Experimental Animal Use	×	KSU-REC008-E (if used)	KSU-REC008-E	×	×
9	Use of Stem Cell, Zygotes, Gametes And Fetuses In Research	KSU-REC009-E (if used)	KSU-REC009-E (if used)	KSU-REC009-E (if used)	×	KSU-REC009-E (if used)
10	Device Use	KSU-REC010-E (if used)	KSU-REC010-E (if used)	KSU-REC010-E (if used)	×	KSU-REC010-E (if used)
11	Use of Drugs and/or Biological Products	KSU-REC011-E	KSU-REC011-E (if used)	KSU-REC011-E (if used)	×	KSU-REC011-E (if used)
12	Request to Amend a Currently-Approved Project	KSU-REC012-E (if needed)	KSU-REC012-E (if needed)	KSU-REC012-E (if needed)	KSU-REC012-E (if needed)	KSU-REC012-E (if needed)
13	Adverse Events (AE), Serious Adverse Events (SAE), and Unexpected AEs Form	KSU-REC013-E *(if needed)*	KSU-REC013-E *(if needed)*	KSU-REC013-E *(if needed)*	×	×
14	Study Status Report for a Clinical Trial	KSU-REC014-E	×	×	×	×
15	Study Status Report for a Medical/Scientific/Humanities/plant Research	×	KSU-REC015-E	KSU-REC015-E	KSU-REC015-E	KSU-REC015-E
16	Request for Sending Human Biological Samples Outside the Kingdom نموذج طلب إرسال عينات حيوية (بشرية) لخارج المملكة العربية السعودية	KSU-REC016-E KSU-REC016-A *(if needed)*	KSU-REC016-E KSU-REC016-A *(if needed)*	×	×	×
17	Request for Re-approval of an Approved Project	KSU-REC017-E *(if needed)*	KSU-REC017-E *(if needed)*	KSU-REC017-E *(if needed)*	KSU-REC017-E *(if needed)*	KSU-REC017-E *(if needed)*
18	Final Report (Study Completion or Termination)	KSU-REC018-E	KSU-REC018-E	KSU-REC018-E	KSU-REC018-E	KSU-REC018-E

مثال لأحد النماذج:

Proposal Application for Research Involving Human Participants

نموذج التقديم لبحث ينطوي على مشاركة بشرية

Form # KSU-REC 002E

King Saud University Vice Rectorate for Graduate Studies & Research Deanship of Scientific Research Research Ethics Committee	جامعة الملك سعود وكالة الجامعة للدارسات العليا والبحث العلمي عمادة البحث العلمي لجنة أخلاقيات البحوث	For REC use only: Full Board [ ] Expedited [ ] Proposal No. _____

Proposal Application for Research Involving Human Participants (Form # KSU-REC 002E)

SECTION I : GENERAL INFORMATION

1. Title of Study:			
English:			
Arabic:			
2. Contact Information:			
1. Principle Investigator (P)			
Name			
ID		Department/College	
Phone No.		Fax No.	
E-mail			
Status	□ Undergraduate Student	□ Hospital Staff	
	□ Graduate Student	□ Post-Doctoral	
	□ Resident/Fellow	□ Faculty	

2. Co-Investigators and Members of Research Team:			
Name	Email Address	Department/College	Role in Project

Study expected start date (Day/Month/Year)	--/--/-- H	--/--/-- G
Study estimated end date (Day/Month/Year)	--/--/-- H	--/--/-- G
Study completion date (Day/Month/Year)	--/--/-- H	--/--/-- G
Submission date (Day/Month/Year)	--/--/-- H	--/--/-- G

SECTION II : COLLABORATING INSTITUTIONS/FACILITIES AND OTHER REC REVIEWS

Will the research be conducted only at KSU/KKUH with no involvement of a collaborating institution?	
□ Yes (if yes, skip to section III)	□ No

If you are collaborating with other sites, provide the name of each institution/facility and describe the type of involvement of each institution (e.g. recruitment, enrollment, consenting, study procedures, follow-up, data analysis). Indicate if REC approval/site permission is attached

Institution Name	Describe Involvement	REC Approval/Site Permission Attached?

International Research:

Will any aspect of the study take place outside the Kingdom? If yes, complete the table below.		□ Yes	□ No
List Location(s)	**Name of Collaborating Institution/Facility**	**Describe Involvement**	**REC/Ethics Approval and/or Site Permission Attached?**

SECTION III: FUNDING INFORMATION

1. Is this research being funded?	□ Yes	□ No
2. If yes, please specify:		
Funding agency		
□ Governmental funding within the kingdom		
□ Private sector funding within the kingdom		
□ International government funding		
□ International private sector funding		
□Under graduate / post graduate student funding		
Total budget of the project:		

SECTION IV: DRUGS/BIOLOGICAL PRODUCTS/DEVICES, BIOLOGICAL SAMPLES, GENETIC TESTING, RADIATION and RADIOISOTOPES, AND EXPERIMENTAL ANIMALS

Does the Proposal involve the use of any of the following? Check all that apply:

1. Drugs/ Device Use		
• A SFDA approved drug or medical device	□ Yes	□ No
• An investigative/unapproved drug, supplement, chemical, biological products, or controlled substances	□ Yes	□ No
• A medical or non-medical device	□ Yes	□ No
• A proprietary product	□ Yes	□ No
• A placebo	□ Yes	□ No
If "Yes" to any of the previous points, please fill the KSU-REC forms # KSU-REC 010E for the use of Devices; AND the KSU-REC form # KSU-REC 011E for the use of drugs and/or biological products in research.		
2. Biological Samples		
Blood, Urine, Tissue, Saliva, etc. (**Either banked or prospectively obtained)**	□ Yes	□ No
If "Yes": - confirm that all relevant personnel have been trained and have an experience in dealing with biological samples. - confirm that all relevant personnel have completed a "Blood borne pathogen training and immunization".	□ Yes □ Yes	□ No □ No

3. Genetic Material Testing			
Genetic testing of biological samples (Blood, Urine, Tissue, Saliva, etc. , or the use of recombinant DNA/Human gene transfer (including use of vectors)	□ Yes	□ No	
If "Yes": A. Specify the genetic testing to be done on these samples.			
B. Will the genetic sample be sent outside the Kingdom?	□ Yes	□ No	
If "Yes", approval from the Local Research Ethics Committee, King Saud University should be obtained before sending the genetic samples outside the Kingdom. Please attach the approval letter.			
C. Will results of genetic testing be reported to subjects?	□ Yes	□ No	□ NA
If "Yes", the following conditions must be met: 1. A specific genetic test is being performed and subjects are notified at the time of the consent what the test is and how the results might affect them. 2. Specify who will transmit the results of the study. 3. Specify whether genetic counselors will be available to subjects.			
4. Stem Cells, Zygotes, Gametes and Fetuses			
The Research project involves the use of stem cells, zygotes, gametes, or fetuses	□ Yes	□ No	
If "Yes", please fill the KSU-REC form # KSU-REC 009E for the use of Stem Cell, Zygotes, Gametes and Fetuses			
5. Radiation or Radioisotopes			
The research project involves the use of Radiation or Radioisotopes	□ Yes	□ No	
If "Yes":			
- Please specify where will the radiation be used (College, and building / room no.):			
- Please specify Name(s) of approved radioisotope permit holder, and the duration of permit:			
- Please specify methods of special handling and disposal of radioactive waste:			
6. Experimental Animals			
The research project involves the use of Experimental Animals?	□ Yes	□ No	
If "Yes", approval from the Local Animal Facility and from the Local Research Ethics Committee, King Saud University should be obtained before the use of experimental animals is initiated. Please fill the KSU-REC form #KSU-REC 008E for Experimental Animal Use in research.			

SECTION V: RESEARCH PROTOCOL AND SIGNIFICANCE

1. **Please provide the proposed project abstract including the following subheadings: Background, objectives, and methods (not more than 300 words)**

2. **Please describe briefly how this study will contribute to existing knowledge in the field.**

3. **Please attach/upload the detailed Research Proposal Form (Form # KSU-REC 003E-A).**

Study protocols should be formatted using Times New Roman font, size 12, double-spaced.

SECTION VI: RISKS AND BENEFITS OF THE PROPOSED RESEARCH

1. POSSIBLE RISKS A. Indicate if the participants might experience any of the following risks:		
i. Physical risk (including any bodily contact or administration of any substance)?	□ Yes	□ No
ii. Psychological risks (including feeling demeaned, embarrassed, worried or upset)?	□ Yes	□ No
iii. Social risks (including possible loss of status, legal risk, privacy and/or reputation as well as economic risks)?	□ Yes	□ No
iv. Are any possible risks to participants greater than those the participants might encounter in their everyday life?	□ Yes	□ No

B. If you checked yes for any questions i – iv above, please describe the risk(s) in the space below		
C. Management of Risk: describe how each of the risks identified above will be managed or minimized. Please include an explanation regarding why alternative approaches cannot be used.		
D. Misrepresentation/Trick: Is there any Misrepresentation/Trick involved in this research?	□ Yes	□ No
i. If Misrepresentation/Trick is to be used in your methods, describe the details of the Misrepresentation/Trick (including what information will be withheld from participants) and justify the use of Misrepresentation/Trick.		
2. POSSIBLE BENEFITS:		
Discuss any potential benefits to the scientific community/society that justify involvement of participants in this study. ***(Please Note: Benefits should not be confused with compensation or reimbursement for taking part in the study).***		

SECTION VII: PRIVACY AND CONFIDENTIALITY

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? □ Yes □ No

2. If yes, select all that apply:

□ Name	□ IP Address
□ Date of Birth	□ Biometric Identifiers
□ Mailing or Email Address	□ Photos/Images/Audio Recording
□ Phone or Fax Numbers	□ Signatures, handwriting samples
□ National ID	□ Any unique identifiers not mentioned above
□ License, Certificate or Vehicle ID	

SECTION VIII: CONSENT PROCESS

1. Informed Consent:

- Will you use a written informed consent document?
  - □ Yes
  - □ No, I am asking a waiver of written informed consent
  - □ Not applicable

2. Written parental permission

- Will you obtain written parental or guardian permission for children, individuals under 18, prisoner and incompetent?
  - □ Yes
  - □ No, I am asking a waiver of written informed consent
  - □ Not applicable

3. Please attach/upload Arabic consent form using the forms provided by the KSU-REC (Form no. KSU-REC 005A, OR KSU-REC 006A)

An English consent form might also be attached/uploaded (Form no. KSU-REC 005E, OR KSU-REC 006E)

SECTION IX: CONFLICT OF INTEREST DISCLOSURE

The REC policy requires that members of the faculty conducting research involving human participants at King Saud University must disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict has to be managed prior to the faculty member's engaged in the research with human participants.		
□ Yes	□ No	Are you, a family member, or spouse the inventor of any products, novel treatment under evaluation, or technology used in the research?
□ Yes	□ No	Do you, or does a family member, or spouse have fiduciary role or have an ownership interest in any entity that provides materials, novel treatment under evaluation, products, technology, or services in the research?
□ Yes	□ No	Do you or does any family member, or spouse receives income/payments from an entity that provides materials, novel treatment under evaluation, products, technology, or services in the research?
□ Yes	□ No	Is the research sponsored by a company for which you, and/or a family member consult, serve on its scientific advisory board, data safety monitoring board, or board of directors or have a paid position?
□ Yes	□ No	Is the research sponsored by a company for which you (or your spouse or your children) hold any ownership interest (stock, not including stock owned through a mutual fund) or from which you are entitled to receive royalties from a licensing agreement?
□ Yes	□ No	Is the research sponsored by a company?
□ Yes	□ No	The value of my remuneration or financial interest exceeds SR 20.000
□ Yes	□ No	Are you, a family member, or spouse receive other remuneration (trips, gifts… etc.)

What is (are) the name(s) of the company or entity for which you will be engaging in the external activity (if applicable)?

Please provide a brief description of the nature of your relationship with the entity, and the amount of your expected remuneration from, or the value of your financial interest in the outside company or entity; if applicable.

Investigators must declare to the KSU-REC of any change in circumstances during the development of, or in the course of a project that would mean that they or their spouse, or family members would receive or hold any of the declarable items described above. Please check the following box if applicable.

□ I have read the above statement on conflicts of interest. I have nothing to declare now and I will immediately declare in writing to the KSU-REC of any future conflicts of interest

SECTION X: PRINCIPAL INVESTIGATOR CERTIFICATION

I agree to:
Comply with the law of Research Ethics Committee on Living Creatures in the Kingdom of Saudi Arabia, and the Implementing Regulation of the Law of Ethics of Research on Living Creatures by the National Committee of Bioethics and the Local Research Ethics Committee on Living Creatures in King Saud University Institutional Review Board (KSU-REC)
I also understand the absolute need to:

1. Design the study with the standards set by the University, the Saudi Food and Drug Administration and other sponsoring agencies.
2. Obtain prior approval from the KSU-REC before amending the research protocol or the approved consent form
3. Report to the KSU-REC in accordance with KSU-REC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants
4. Submit a progress report both annually and whenever requested by the KSU-REC.
5. Submit the Re-Approval form/Completion Form as needed
6. Ensure that each individual listed as study personnel in this application is knowledgeable of the study procedures described in the proposal
7. Include the KSU-REC approval no. in any published paper coming out of this study
8. Abide to the items and conditions listed in the attached files, including but not limited to the study proposal, informed consent, etc.
9. Abide timely with all the requested reports or forms, as failure to do so will entitle the KSU-REC to terminate the approval already granted to the study under progress.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Principle Investigator (PI) Name	**PI Signature**	**Date**
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Student Investigator Name*	**Student Investigator Signature**	**Date**
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Co-Investigator Name	**Co-Investigator Signature**	**Date**
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**(Only for student-initiated Research)*

For more information, please visit the website of the Research Ethics Committee in King Saud University (http://dsrs.ksu.edu.sa/ar/research_ethics_comm.)

Form # KSU-REC 002E, Version 1.5, Last updated 15 April, 2014

For REC use only:
Full Board [ ]
Expedited [ ]
Proposal No. _____

Informed Consent Checklist
Form # KSU-REC 004-E

Yes	No	NA	ITEMS
			REQUIRED ELEMENTS
☐	☐	☐	The expected duration of the participant 's participation
☐	☐	☐	A description of the procedures to be followed
☐	☐	☐	Identification of any procedures which are experimental (vs. standard care)
☐	☐	☐	A description of any reasonably foreseeable risks or discomforts to the participant
☐	☐	☐	A description of any benefits to the participant or to others which may reasonably be expected from the research
☐	☐	☐	A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant
☐	☐	☐	A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
☐	☐	☐	If the research is subject to SFDA regulation, a statement that notes the possibility that SFDA may inspect the records
☐	☐	☐	For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs
☐	☐	☐	An explanation as to whether any medical treatments are available if injury occurs, what they consist of, or where further information may be obtained
☐	☐	☐	An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights
☐	☐	☐	Who to contact in the event of a research-related injury to the participant
☐	☐	☐	A statement that participation is voluntary
☐	☐	☐	A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
☐	☐	☐	A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled
☐	☐	☐	A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable
☐	☐	☐	The subject's responsibilities
☐	☐	☐	Any additional costs to the participant that may result from participation in the research
☐	☐	☐	The anticipated pro-rated payment, if any, to the subject for participating in the trial
☐	☐	☐	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?
☐	☐	☐	A statement that "Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent"
☐	☐	☐	The approximate number of participants involved in the study (at this site and all sites)
☐	☐	☐	A statement that the study participant consents for the use of his/her samples later for other projects by the study investigators and their collaborators

Yes	No	NA	ITEMS
	ADDITIONAL ELEMENTS (If applicable)		
☐	☐	☐	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
☐	☐	☐	The consequences of a participant's decision to withdraw from the research
☐	☐	☐	Procedures for orderly termination of participation by the participant
☐	☐	☐	Possible consequences of discontinuing current medication(s)

15 min: Team Work Activity: Fill informed consent forms (English and Arabic for a medical studies

نشكر لكم
حسن استماعكم

Thank You For Your Attention