

**Request for Re-approval of an Approved Project
Form # KSU-REC 017-E**

General Information			
Study Title:			
Principal Investigator:			
Department/College:			
Mailing address:			
Phone:		Fax:	
Email:			

I certify that I have thoroughly reviewed the information provided on this report form. I also certify that the information provided is true and accurate.

Signature of Principal Investigator

Date

1. Provide a brief summary of the purpose of the study, results to date and expected time for completion (not more 500 words)

2. Review Category:

This project qualifies for	<input type="checkbox"/> Full Review	
	<input type="checkbox"/> Expedited Review: select from list	
Research was originally reviewed and approved under expedited review*:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Expedited Category:		
The research is permanently closed to the enrollment of new subjects; and , the research remains active only for long-term follow-up of subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
The remaining research activities are limited to data analysis only.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

* **Expedited Review:** An evaluation carried out by the local committee chairman, or by a committee member designated by him, of a new research project or modifications of a previously approved research where potential risk to the human subject does not exceed minimal risk

3. Initial REC approval on:

4. Submit copy of current consent document (approved on)

5. Are you planning to implement any of the following points on the already approved protocol?

a. New advertisements / recruiting materials	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. Major protocol deviations	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. Protocol amendments	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. Change of principal investigator	<input type="checkbox"/> Yes	<input type="checkbox"/> No
e. Change in other study staff	<input type="checkbox"/> Yes	<input type="checkbox"/> No

6. Specific risk considerations.

1. Were there any unanticipated problems involving risk to subjects or others (e.g., greater AE/SAE incidence than expected, breach of confidentiality, or cost to subject)?

Yes No

If yes please explain

2. Has any information been provided to subjects that might affect their willingness to stay in the study?

Yes No

If yes please explain

3. Have any subjects sought compensation for research-related injury or made complaints regarding the conduct of the study?

Yes No

If yes please explain

4. Has anything occurred in the study that you believe might alter the study's original risk/benefit status?

Yes No

If yes please explain

7. Will the subjects' recruitment process include any subject from vulnerable groups?

Yes No

If Yes, check all that apply:

<input type="checkbox"/> abortuses	<input type="checkbox"/> KSU employees or students
<input type="checkbox"/> AIDS/HIV patients	<input type="checkbox"/> minorities
<input type="checkbox"/> children	<input type="checkbox"/> physically disabled
<input type="checkbox"/> cognitively impaired	<input type="checkbox"/> pregnant women
<input type="checkbox"/> elderly	<input type="checkbox"/> prisoners
<input type="checkbox"/> institutionalized (not prisoners)	<input type="checkbox"/> other:
<input type="checkbox"/> fetuses	
<input type="checkbox"/> in-vitro fertilization	

Created by [Name]		Approved by (PI) [Name]	
Signature		Signature	
Date		Date	

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