مستشفى الملك فيصل التخصصي ومركز الأبحاث
King Faisal Specialist Hospital & Research Centre
Gen. Org. مؤسسة عامة

OFFICE OF RESEARCH AFFAIRS
MBC ✉ 03, Fax 27894, Ext ☎32969

INTERNAL MEMO

TO: **Shouki Bazarbashi, MD**
Head, Section of Medical Oncology
Oncology Centre

DATE: 06 Muharram 1430
03 January 2009

FROM: **Mohamed M. Al Turki, CCRP**
Co-Director
Office of Research Affairs

REF: ORA/0017/30

SUBJECT: **Project # 2081 068**
PHASE I-II TRIAL OF CAPECITABINE (XELODA®), OXALIPLATIN AND IRINOTECAN IN COMBINATION WITH BEVACIZUMAB IN I[st] LINE TREATMENT OF METASTATIC COLORECTAL CANCER

Further to our memo, ORA/1856/29 dated 12 November 2008, the revised proposal and revised Consent Form (Ref: KFCC-RU: 306.29, received on 24 November 2008) were reviewed by the Clinical Research Committee (CRC) and Research Ethics Committee (REC) 17 and 23 December 2008, respectively.

It is my pleasure to inform you that both Committees have recommended the revised proposal and revised consent from for approval; and I would like to take this opportunity to congratulate you on behalf of the Research Advisory Council (RAC).

Please be informed that in conducting this proposal, the Investigators are required to abide by the rules and regulations of the Government of Saudi Arabia, KFSH&RC, and the RAC. Further, you are required to submit a Progress Report by 23 November 2009, so it will be reviewed by RAC without lapse of approval. The approval of this proposal will automatically be suspended on 23 December 2009, pending the acceptance of the Report. You also need to notify the ORA as soon as possible in the case of:

1. Any amendments to the project.
2. Termination of the study.
3. Any serious or unexpected adverse events.
4. Any event or new information that may affect the benefit/risk ratio of the proposal.

Please observe the following:

1. Personally identifying data should only be collected when necessary for research.
2. The data collected should only be used for this proposal.
3. Data should be stored securely so that only a few authorised users are permitted access to the database.
4. Secondary disclosures of personally identifiable data are not allowed.
5. Copies of the signed Consent Form should be kept in the research subjects' Medical Records; and the consenting process should be documented in the Medical Records.

Thank you

Attachment: Approved Consent Form
SUAE

cc: Chairman, Clinical Research Committee
Chairman, Research Ethics Committee
Chairman of PI(s)
Research Unit, Oncology Centre

ORA
A
C

30 0017 20810 68 Dr. Bazarbashi aprvl CRC REC

E-mail: ora@kfshrc.edu.sa