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**UNIT OF
BIOMEDICAL ETHICS**
Research Committee

Initial Approval

TO: Principal Investigator: Prof. Abdulmoein Eid Al-Agha (Pediatric)
Co-investigator: Dr. Abdulaziz M. Alkahtani
Co-investigator: Dr. Ahmed Ali Basalama
Date: Wednesday, June 22, 2016

From: Professor. Hasan Alzahrani
Co-investigator: Fotoun A. Aqeel
Co-investigator: Esraa A. Kashkari
CC: Vice-Dean, University / Hospital Director & Academic Affairs & File & Mentoring Committee

RE: "Community awareness of sources and side effects of Xenoestrogen on female early puberty and female estrogen dependent cancer in Makkah region: A Cross sectional study" (Reference No 261-16)

The above titled research/study proposal has been examined with the following enclosures:

- The Study Protocol.
- Informed Consent Form.

The REC recommended granting permission of approval to conduct the project along the following terms:

1. The PI and Co- Investigator are responsible to get Academic Affairs, hospital and departmental approval.
2. The Investigators will conduct the study under the direct supervision by the Prof. Abdulmoein Eid Al-Agha .
3. Provide to committee "Continuing Review Progress Report" every 3 months.
4. Any amendments to the approved protocol or any element of the submitted documents should NOT be undertaken without prior re-submission to, and approval of the REC for prior approval.
5. Monitoring: the project may be subject to an audit or any other form of monitoring by the REC.
6. The PI is responsible for the storage and retention of original data of the study for a minimum period of five years.
7. The PI is expected to submit a final report at the end of the study.
8. The PI must provide to REC a conclusion abstract and the manuscript before publication.
9. To follow all regulations issued by the National Committee of Bio & Med ethics - King Abdul Aziz City for Science and Technology.

The Organization & operating procedure of the KAU. Faculty of Medicine - Research Ethics Committee (REC) are based on the Good Clinical Practice (GCP) Guidelines.
PLEASE NOTE THAT THIS APPROVAL IS VALID FOR ONE YEAR COMMENCING FROM THE DATE OF THIS LETTER.

Professor Hasan Alzahrani

Chairman of the Research Ethics Committee

(HA-02-J-008) No of Registration At National Committee of Bio. & Med. Ethics.
Mohammed S. ALsearee (Reference No 271-16)

