11th HS-PAC Agenda-OTHER ITEMS

Place: AIIMS, New Delhi

1. **Budget Revision under Non-recurring head:**
   File no: EMR/2016/002523
   PI Name: Ramesh Kumar Radhakrishnan

   **Title of the project:** Enriched physical activity in conjunction with Fucoidan from Fucus vesiculosus on Neuro-angiogenic factors mediated cognitive restoration in vascular dementia model of rat.

   **Recommended Budget:** at 7th HS-PAC meeting.

   The committee recommended the following budget for a period of three years:

   - **Manpower:** salary as per norms
     - Junior Research Fellow: 1
   - **Equipment Details:** Rs. 1100000
     - Rotary Microtome: 1
     - Operating surgical microscope: 1
     - Minor equipment (Deep freezer: 20, Shaker, Rocker): 3
   - **Consumables:** Rs. 1000000
   - **Travel Cost:** As per norms
   - **Contingencies:** As per norms
   - **Overhead:** As per norms

   Additional Budget requested by the Investigator under non-recurring head: Rs. 3,00,000/- (four lakhs only) apart from the committee recommended Rs. 11,00,000/-.

2. **HS-PAC review committee’s observations and opinion about the project entitled**

   **Title of the project:** “A Randomised controlled trial of neoadjuvant chemotherapy with FEC vs Concurrent Chemo-Radiation with FEC in locally advanced breast-cancer and identification of predictive markers for pathologic complete response”

   **Investigator details:** Dr. Veluswami Sridevi, Scientist, Cancer Institute (WIA), Chennai, Tamilnadu.

   **RECOMMENDED OBJECTIVES:**
   1. To compare the clinical efficacy of neo-adjuvant chemotherapy as against neo-adjuvant concurrent chemo-radiation in Locally Advanced Breast Cancer.
   2. To compare the toxicities of the two therapy arms
   3. To compare the Pathologic Complete Response in the two arms
4. To compare the Disease Free Survival and Overall survival in the two arms (this objective will require a longer follow-up)

5. To do a Proteomics profiling of the pre-treatment tumour tissue sample and identify and validate characteristic signatures which can help predict Pathologic Complete Response (pCR). Additionally, the proteins contributing to the peaks will also be identified and validated.

PAC comments:
1. 70 study subjects have been recruited out of 300 samples, so far. Yet to recruit the few more study subjects to achieve the statistical significance.
2. LC-MS has been standardized
3. Committee advised the investigator and co-investigator to expedite the work progress.
4. 5th objective has to be expedited. Prof. Sudeep Gupta opinion has to be sought.
GRADE: Satisfactory

Title of project: Magnetic Resonance(MR) Multi Parametric Approach to the Study of Breast Cancer and its Correlation with Molecular Markers

PI details: Dr. N. R. Jagannathan, Professor & Head, Department of NMR & MRI Facility, All India Institute of Medical Sciences, New Delhi – 110029

3rd HS-PAC Meeting comments: Out of 5 objectives mentioned only objective 1 partly has been completed. There was no data with regard to NACT induced changes and their correlation with pathological response and survival. No data has been provided in regards to objective # 4. Investigators failed to mention the standardization protocol for the molecular markers that has been planned for the current study. The report talks about tCHO and ADC being able to distinguish between normal benign and malignant lesions as a new finding. There was a similar publication in 2009 using 1.5 tesla unit. While they should have used 3T MRI, but the
The report talks about only 1.5 T MRI. The total sample number given in proposal is 110 cancer study subjects. However, after a period of 2 years, they have only 63 study subjects. Some of the publications mentioned in the proposal are not related to the current project. One of the articles is a review article which doesn’t have any impact factor. The investigator has publications in 2006, 2009, 2010 looking at the DWI, MRS, imaging changes associated with NACT and another in 2011 on therapeutic response in breast cancer. The above mentioned articles are published before Sep 2013, current project date of sanction. In view of above comments, PI should be called for presentation for the next PAC meeting and project should be reviewed again. The comments also should be communicated to the PI.

**Committee recommendation:**

**AS per 3rd HS-PAC recommendation** PI has been called for presentation before the committee to present his work progress.

**Current Status:**

PI has submitted the detailed report and settled the account.