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To: Deans of Colleges

From: Tim Tracy, Interim Provost

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**Oversight of Cancer Clinical Trials by the Markey Cancer Center
Effective May 10, 2013**

The National Cancer Institute (NCI) requires that NCI-funded cancer centers involved in clinical research provide adequate internal oversight of the scientific aspects of all the cancer clinical trials in the institution or institutions that formally comprise the center, as well as the data and safety monitoring of these trials. In anticipation of receipt of NCI designation and to comply with this requirement, the Markey Cancer Center will have formal oversight over all clinical cancer trials across the UK campus and involving UK investigators, effective immediately. As part of this oversight, the MCC Protocol Review and Monitoring System (PRMS) will scientifically evaluate all cancer center trials derived by institutional investigators and supported from institutional sources. The intent of this scientific review is not to duplicate formal peer review, but to facilitate the development of excellent science involving cancer and participants with cancer. This oversight includes both interventional and non-interventional research, but does not include preclinical cancer investigations.

Interventional cancer research requires:

- One of the following levels of review by the Protocol Review and Monitoring Committee (PRMC):
 - Full review (for investigator-initiated studies, industry collaborations and studies that have not undergone previous peer-review) in the presence of the full PRMC. The PRMC assesses scientific rationale, study design, expected accrual rates, biostatistics calculations and feasibility for completion within a reasonable time period.
 - Expedited review (for previously peer-reviewed protocols and studies supported by the various NIH mechanisms (e.g., R01s, U01s, U10s, P01s, and P50s, etc.), other national funding agencies or which are low-risk facilitated by the PRMC chair or co-chair.

- Exempt (those that do not require individual signed consent) as determined by the PRMC with the assistance of the IRB. Non cancer research is also exempt.
- Maintenance by the MCC of a minimal dataset of information for all cancer clinical trials including: accrual, basic demographic data of participants (non-protected health information)
- Data and Safety Monitoring is required for all types of interventional cancer clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). The MCC provides DSM for all cancer clinical trials commensurate with risk, and assuring of safety and quality of all participants in clinical cancer research, complimentary to the UK Institutional Review Board's functions.

Non-interventional cancer research (e.g., epidemiologic, outcome, observational studies) requires minimal oversight:

- Maintenance by the MCC of a minimal dataset of information for all cancer clinical trials including: accrual, basic demographic data of participants (non-protected health information)