***Deans UPDATE to PRA Determination Criteria 4/2015:***

*Prospective reimbursement analysis (PRA) development is an integral process supporting our clinical research teams. The analysis for each study results in a determination of whether charges for patients enrolled in clinical studies should be billed as standard of care or research based upon the protocol, budget and contract. The implementation of the PRA process has contributed to a nearly 100 percent increase in the number of clinical trials started last year compared to 2012. Use of the Clinical Research Management System (CRMS) as a single database for all patients currently in clinical research studies now includes 140,000 patients. CRMS serves as the source for all research information linked to Epic.*

*As a result of our adoption of Epic, we must realign our processes in a manner that enhances our ability to track patients enrolled in clinical research protocols. Protocols started prior to 2008 and research protocols with healthy volunteers and sample collections during routine care will be evaluated by CRMS A protocol billing grid will be created if potential research-related charges are identified. A full PRA will not be required.*

*A key change for study team members is that participants in studies with a protocol billing grid must be entered and kept updated in CRMS; use was previously optional. Information in CRMS interfaces with Epic to create the “Research: Active” header that triggers our billing compliance connection. CRMS will notify you if your study requires a protocol billing grid and use of CRMS. The notification will clearly define when a protocol billing grid only versus a PRA is required.*

*This new policy assures that all patients in an active status on a research study will be flagged in Epic. The flag is essential for patient safety and correct billing.*

*Your continued support and cooperation is greatly appreciated as we continue to improve the administrative processes that support your clinical research. If you have questions regarding the new PRA determination criteria, please contact Scott Streibich at**sstriebich@jhmi.edu**or 410-502-0124, or Karen Roz at**rozka@jhmi.edu**or 410-955-7682.*

*Best regards,*

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