

DF/HCC

DANA-FARBER / HARVARD CANCER CENTER

## Office for the Protection of Research Subjects

### **OPRS ALERT**

#### *Changes in Dose Preparation/Administration*

The DFCI IRB has learned that some sponsors are sending study teams information which affects drug preparation/administration without an amendment and without appropriate changes to the protocol or pharmacy manual. Even though sponsors may not view these changes as an amendment, at DF/HCC it will be considered as such and must be submitted to OPRS. This is critical for patient safety to ensure that all clinicians are aware of the changes; the proper Alert Pages are generated or updated, and appropriate changes in computer order entry templates are made. The only time that a drug preparation/administration change may be implemented without prior notice to OPRS is to eliminate an immediate hazard to subjects. In these cases, nursing and pharmacy must still be notified of the change and an amendment reflecting the change must be submitted to OPRS as soon as possible.

Please contact OPRS with any questions.

**The Office for the Protection of Research Subjects  
Communications Group  
20 Overland Street  
2nd Floor  
Boston, MA 02115**

DF/HCC  
Member  
Institutions

Beth Israel Deaconess Medical Center / Brigham and Women's Hospital / Children's Hospital Boston /  
Dana-Farber Cancer Institute / Harvard Medical School / Harvard School of Public Health /  
Massachusetts General Hospital

NCI  
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A Comprehensive Cancer  
Center Designated by the  
National Cancer Institute