

## UMC IRB Updates – October 2015

### Policies and Procedures Manual:

- Please note the change to Section 29. **UNANTICIPATED PROBLEMS AND ADVERSE EVENTS**
  - There are substantial changes to the UMC IRB reporting requirements and definitions to Unanticipated Problems and Adverse Events
  - These changes are effective immediately

### Forms and Templates: Reportable Events

- To align with the UMC IRB P&P changes with regard to Unanticipated problems the following forms have been added:
  - UMC IRB Guidance Investigator Reporting Obligations - version 1, dated 06/2015
  - Reportable Events Submission Form - version 1.6, dated 06/2015
  - UMC Sample Reportable Event Summary - version 1, dated 06/2015
- When submitting Unanticipated Problems, Adverse Events and Reportable Events the above reference forms and guidance must be completed and submitted as directed in the Guidance and as outlined in the update Policies and Procedures Manual Section 29