What can BUMC investigators do?
With the new changes in policy for reporting of UPs and AEs/SAEs, BUMC investigators may be left asking the question, "what do I need to do with this information?". Here are some suggestions:

- **Stop submitting individual AE reports to the IRB.** Review each AE and only submit it individually to the IRB if it meets the definition of a UP. If so, submit it within 2 business days using the UPSER/Adverse Event form. Be sure to state on the form why it meets the definition of an UP and explain how protocol and consent will be changed.

- **Submit to the IRB, at the time of the Progress Report, a summary of all AEs that have occurred, using the UPSER/Adverse Event form.** This summary must include an evaluation of the AEs by the data safety monitor or investigator as to whether any or all the AEs indicate that there is a new or previously unrecognized risk to subjects and whether or not the protocol or consent have to be modified to include these risks.

- **Submit to the IRB all DSMB reports, DMC reports or other data safety monitoring committee reports when they become available using the UPSER/Adverse Event form.** The most recent report must be submitted by the time of the Progress Report, using the UPSER/Adverse Event form, so it is available to the IRB for review.

- **Review your data safety monitoring plans (DSMPs) for all active studies.** Verify that the DSMB, DMC, AE Monitoring Committee has met according to the plan described in the IRB protocol.

- **If the DSMB (or other AE monitors) have not met according to the plan (DSMP) described in the IRB approved protocol submit a deviation report IMMEDIATELY via INSPIR.** Contact Russell Gontar, OCR Manager of Quality Assurance, at 617-414-1336.

- **If you are a sponsor-investigator (hold an IND or a IDE), review the FDA requirements for AE reporting and check to be sure that you have complied with all these requirements.** If you have not been reporting AEs as required by the FDA regulations, IMMEDIATELY submit a deviation report to the IRB via INSPIR.

- **When submitting a new IRB protocol, carefully consider the DSMP.** Make sure that the plans are clear, precise and reasonable. If you indicate that the DSMB will meet monthly, you will be held to it and you may be setting yourselves up for failure. At the time of EACH continuing review, review the summary of adverse events and compare it to the INSPIR protocol (Potential Risk/Discomforts section) and the consent form (risk section). Verify that all the research risks are described in the protocol and the consent and that no new risks have been identified by the AE reports.

- **Send a copy of the “to whom it may concern” letter posted on the IRB website to your sponsor explaining the change in BUMC policy for reporting UPs, AEs and SAEs if they have questions about the changes to the IRB policy.**