NIH Notice Regarding FDA Correspondence

1. On September 22, 2000, the NIH issued a notice to all NIH grantees and contractors regarding letters or notices from the FDA.
2. The notice reminds awardee institutions that in compliance with 45 CFR 74.51(f), FDA communications to the awarding Institute(s) or Center (s) must be reported to the NIH within 72 hours of receipt.
3. By statute, the FDA communicates with the sponsor of the IND or IDE. The sponsor may or may not be the awardee institution or the NIH funded Principal Investigator. The FDA requires that the sponsor keep all principal investigators informed during the course of the study.

Therefore, to ensure compliance with these regulations and to ensure that the Einstein IRB is aware of all FDA correspondence, all Principal Investigators who receive any of the FDA correspondence delineated below must immediately forward such notices to the Einstein IRB Administrative Office, along with documentation, if applicable, that these notices were reported to the NIH:

1. Warning letters: letters that are sent to you and/or the commercial sponsor.
2. Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE letters).
3. Notice of Opportunity for Hearing (NOOH)
4. Notice of Disqualification
5. Consent Agreements
6. Clinical hold letters that pertain to breaches of either Good Manufacturing Practices, Good Clinical Practices, or other major issues requiring significant changes in the protocol.