Policy for Informing Research Participants of Protocol Amendments and/or New Risk Information

Protocol Amendment:
It is the policy of the Einstein IRB that should a protocol be amended during the course of a study, and the informed consent revised, research subjects currently enrolled in the study are not routinely required to sign the revised informed consent document. Such a decision is made by the Einstein IRB on a case-by-case basis. In specific circumstances, re-signing of a consent document may be required by the Einstein IRB.

New Information About Risks or Benefits:
It is also the policy of the Einstein IRB that should information concerning possible new risks to research subjects in a study become known, such information shall be provided in a written statement given to all subjects currently enrolled in the study, and when applicable, to those who previously participated in the study. This statement shall also reiterate the subjects' right to withdraw from the study at any time without any loss of benefits to which the subjects would otherwise be entitled.

If there is any potential for immediate harm/risk to the subjects, the PI should notify the subject as soon as possible and document the contact.

In the event of a drug/device recall in a study conducted at the Montefiore Medical Center, the PI needs to contact MMC Risk Management as well as the Einstein IRB.

In the event of a drug/device recall in a study conducted at Yeshiva University, the PI needs to contact General Counsel as well as the Einstein IRB.

In the event of a drug/device recall in a study conducted at the Jacobi Medical Center or the North Central Bronx Hospital, the PI needs to contact HHC Risk Management as well as the Einstein IRB.

Note: All protocol and consent changes require Einstein IRB approval. Refer to the Amendment Policy.