Human Subjects Research: Reporting Requirements

Timing	Reporting Requirement
Reports Required Immediately or Within 24 Hours	• All FDA submissions, reports, or correspondence
	• **Required Time Sensitive Notifications** are FDA safety reports of serious adverse events under IND or IDE
	• Notification to BU of an FDA or EMA audits is required within 5 days of a scheduled audit or site visit OR within 12 hours of an ad hoc audit or site visit
Reports Required Within 3 Business Days of Occurrence	• Major changes to the status of IRB approvals and ongoing protocols
	• Any reviews by an institutional biosafety committee or the NIH Recombinant DNA Advisory Committee
Monthly Reporting	• Monthly technical/progress reporting as outlined in Attachment 4 & 6, including a comprehensive status update of clinical studies actively enrolling patients for each study site
Annual Reporting	• Continuing IRB review by each institution involved in the research or the central IRB, if review is ceded to a single IRB
	• Adverse events documented during the trial and which are reportable in the annual IND or IDE report
Other Ad Hoc Reporting	• Ongoing safety reporting for research not performed under an IND/IDE
	• Ad hoc reporting as requested under Attachment 4a regarding clinical study information
	• A written report when the PD completes a Milestone
	• A final technical/progress report is required to be submitted within 30 days after the end of the period of performance