Human Subjects Research: Monitoring Requirements

Form	Expectations
Bi-Weekly Clinical Teleconferences	• PDs will be expected to participate in calls every two weeks (in addition to CST calls) at least one month prior to study start and through final study report.
	• PDs will be expected to provide status updates about the trial and report findings.
	• PDs will be expected to circulate an agenda in advance and email minutes in follow up to the call.
	• At least one PD expert associated with the trial will be expected to provide this update; BARDA clinical experts and a CARB-X representative will participate.
Non-HSR Specific Monitoring	• Monthly Company Support Team Meetings, to provide support and guidance with respect to the position of HSR work in the overall PD program.
	• Establishment or demonstration of an SAB with adequate oversight over HSR work.
Independent Monitoring	• *This is strongly recommended* for any clinical research involving more than minimal risk to volunteers.
	• The type of monitoring appropriate for the research should be determined jointly by the PD and BU prior to enrollment, and may take the form of an Independent Safety Monitor, Committee, or DSMB.
	• If independent monitoring is used, 1) PD should inform BU of any upcoming site visits or audits; 2) BU and BARDA may attend such site visits or audits; and 3) The PD should provide a written summary to BARDA of all monitoring reviews within 3 days of the review.