Events Reportable to the IRB

Type of Report	Submitting Party	Reporting Timeframe	Form
Any pending or ongoing legal, regulatory, or professional actions or restrictions related to the practice of medicine or research at the site(s)	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
Financial Conflict of Interest	Principal Investigator/Study Staff *(or immediate family member)*	Immediately *(during the course of the study or within one year after the last participant completed the study)*	Financial Disclosure Form
Any study hold/suspension or termination imposed by a regulatory agency, the sponsor/CRO, investigator, or other reviewing IRB	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
Significant Protocol Deviation*	Principal Investigator/Site	Within 10 business days of when the site became aware of the deviation	Reportable Events Form
Sponsor-Granted Protocol Exception	Principal Investigator/Site	Prior to implementation	Sponsor-Granted Exception Report
For investigational devices, a deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency	Principal Investigator/Site	No later than 5 working days after the emergency occurred	Reportable Events Form
Serious Adverse Event (SAE)*	Principal Investigator/Site	Within 10 business days of when the site became aware of the event **(Fatal or life-threatening events should be reported immediately)**	Reportable Events Form
External Adverse Events *(e.g. IND Safety Reports, MedWatch Reports)**	Sponsor/CRO	Within 10 business days of receipt	Reportable Events Form
Unanticipated Adverse Device Effect	Principal Investigator/Site	Within 10 business days of when the investigator first learns of the event	Reportable Events Form
Other Unanticipated Problems*	Principal Investigator/Site	Within 10 business days of when the site became aware of the event	Reportable Events Form
Allegation of finding of noncompliance	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
Incarceration of a participant involved in a protocol not IRB approved to enroll prisoners	Principal Investigator/Site	Within 10 business days of when the site became aware of the event	Reportable Events Form
Change made to the research without prior IRB approval in order to eliminate apparent immediate harm	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
Revisions to the IRB-approved protocol or informed consent document	Principal Investigator/Site or Sponsor/CRO	Prior to implementation	Modifications and Amendments Submission Form
New or updated study product information *(e.g., investigator's brochure, package insert, device instructions for use)*	Sponsor/CRO	Promptly	Modifications and Amendments Submission Form
Change in Principal Investigator	New Principal Investigator	Prior to implementation	Submission Application for the Investigator/Site

Change in Site Information *(e.g. change in research site location)*	Principal Investigator/Site	Prior to implementation	Modifications and Amendments Submission Form
Planned increase in enrollment (over 10%)	Principal Investigator/Site or Sponsor/CRO	Prior to implementation	Modifications and Amendments Submission Form
Change in planned enrollment of vulnerable populations	Principal Investigator/Site or Sponsor/CRO	Prior to implementation	Modifications and Amendments Submission Form
New/revised study or recruitment materials	Principal Investigator/Site or Sponsor/CRO	Prior to implementation	Modifications and Amendments Submission Form
Routine data and safety monitoring reports	Sponsor/CRO	Submit with the Study Status Report at continuing review	
Sponsor Continuing Review	Sponsor/CRO	By the Study Status Report Due Date	Study Status Report
Site Continuing Review	Principal Investigator/Site	By the Study Status Report Due Date	Study Status Report
Single-Site Continuing Review	Sponsor-Investigator	By the Study Status Report Due Date	Study Status Report
Site Final Report	Principal Investigator/Site	Upon completion of the study at your site	Site Final Report

**Please refer to the Sterling IRB Handbook for definitions and examples of such events*