Sterling Achieve More. IRB

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Events Reportable to the IRB

Type of Report	Submitting Party	Reporting Timeframe	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
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
Unanticipated Problems Involving Risks to Subjects or Others / New or Increased Risk	Principal Investigator/Site	Within 10 business days of when the site became aware of the event	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
Urgent data and safety monitoring reports *(e.g. reports indicating an UPIRSO)*	Sponsor/CRO	Within 10 business days of receipt	Reportable Events Form
Routine data and safety monitoring reports	Sponsor/CRO	Submit with the Sponsor Continuing Review Status Report at continuing review	
Financial Conflict of Interest	Principal Investigator/Sub-Investigator *(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
Change in Site Information *(e.g. change in sub-investigator, research site location)*	Principal Investigator/Site	Prior to implementation	Change in Site Information Form
Change in Principal Investigator	New Principal Investigator	Prior to implementation	Submission Application for Change of Principal Investigator
Change in Principal Investigator – *Registry Study*	New Principal Investigator	Prior to implementation	Registry Study Submission Application for Change of Principal Investigator *(use only for registry studies)*
Any event that requires prompt reporting according to the Sponsor	Principal Investigator/Site	Within 10 business days of when the site became aware of the event	Reportable Events Form
Complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff	Principal Investigator/Site	Within 10 business days of when the site became aware of the event	Reportable Events Form
State medical board or federal agency action *(e.g., Form FDA 483, FDA Warning Letter, NIDPOE, medical license action, medical board order or consent agreement)*	Principal Investigator/Site	Within 10 business days	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
Sponsor imposed suspension or termination	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
A breach of confidentiality	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
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
Recalls / Withdrawals / Clinical Holds	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
Reports, publications, interim results or findings that indicate an unexpected change to the risks or potential benefits of the research *(e.g. DSMB reports and recommendations, Regulatory Agency Public Health Advisory)*	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form
New or updated study product information *(e.g. Revised Investigator's Brochures, Revised Label/Package Insert, Revised Device Manual)*	Sponsor/CRO	Promptly	Modifications and Amendments Submission Form
Information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study	Sponsor/CRO	Promptly *(during the course of the study and for two years after the completion of the study)*	Please refer to the New Study Submission Application
Sponsor Continuing Review	Sponsor/CRO	By the Sponsor Continuing Review Status Report Due Date	Sponsor Continuing Review Status Report
Site Continuing Review	Principal Investigator/Site	By the Site Continuing Review Status Report Due Date	Site Continuing Review Status Report
Site Final Report	Principal Investigator/Site	Upon completion of the study at your site	Site Final Report
Single-Site Continuing Review	Sponsor-Investigator	By the Single-Site Continuing Review Status Report Due Date	Single-Site Continuing Review Status Report
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/revised study or recruitment materials	Principal Investigator/Site or Sponsor/CRO	Prior to implementation	Modifications and Amendments Submission Form
Termination or suspension of the study by the Principal Investigator without prior agreement of the Sponsor *(Sterling IRB and the Sponsor must be notified)*	Principal Investigator/Site	Within 10 business days	Site Final Report
Withdrawal of approval from another IRB	Principal Investigator/Site or Sponsor/CRO	Within 10 business days	Reportable Events Form