Requirements Document

Reportable Events Requirements Document

Page	Question	Requirements
1A	**Western IRB Study: Reporting adverse events and unanticipated problems involving risk to subjects or others** In the event of an adverse event or unanticipated problem involving risks to subjects or others, follow the instructions on the following Western Institutional Review Board (WIRB) website: http://www.wirb.com/Pages/DownloadForms.aspx If the occurrence is serious (deaths or life-threatening events) **and** occurred at a Rutgers performance site, a copy of the WIRB report form must be sent within twenty-four (24) hours of discovery by either of the following methods: Email: vegacl@ca.rutgers.edu Fax: 973-972-0906, ATTN: Rutgers WIRB Coordinator Mail: Human Subjects Protection Program, ATTN: Rutgers WIRB Coordinator, Stanley S. Bergen Building, Suite 507, Newark Campus **At this point, Click on finish, and return to the "Reportable Events Workspace". You must then click on the "Withdraw" activity, and follow the instructions listed above.**	Display for WIRB studies only. Button should say Finish instead of Continue. For all non-WIRB studies continue with page 2.
2A	**Reportable Event Information** Study ID: Study Title:	Study ID and Title should be pre-populated
2B	* Short title of event:	
2C	* Submission Type: ○ Acknowledgement Request ○ Data Safety Monitoring Report ○ Protocol Deviation/Violation ○ Unanticipated Problem	Acknowledgement Request branches to page 3. Data Safety Monitoring Report branches to page 4 Protocol Deviation/Violation branches to page 5 Unanticipated Problem branches to page 9

3A	**Acknowledgement Request** * Describe acknowledgement request:	
3B	Upload any supporting documents for this request:	Branches to page 19.
4A	**Data Safety Monitoring Report** * Date report was received by investigator:	
4B	* Upload DSMB Report:	
4C	* Does the report indicate any increased risk to the subject population? o Yes o No	
4D	If yes, please describe any increased risk to the subject population:	
4E	* Are changes to the study recommended based upon this report? o Yes o No	
4F	If yes, please describe the changes recommended based upon this report:	Branches to page 19.
5A	**Protocol Violation/Deviation** * Date of protocol violation/deviation:	
5B	* Date event reported to PI:	
5C	* Nature of Deviation: Describe the deviation(s)/violation(s), including date(s), explanation of why it occurred, and the outcome.	
5D	* Did deviation(s)/violation(s) affect subject safety? o Yes o No	
5E	If yes, please describe:	
5F	**Protocol Violation/Deviation - Sponsor Notification** * Was sponsor notified? o Yes o No o N/A	If Yes, branch to page 6 If No, branch to page 7 If N/A, branch to page 8

6A	**Protocol Violation/Deviation - Sponsor notified** * Provide date of sponsor notification:	
6B	* Provide sponsor response:	
6C	* Upload documentation from sponsor concerning this deviation/violation:	Branches to page 19.
7A	**Protocol Violation/Deviation - Sponsor not notified** 1.0 * Explain why sponsor was not notified	Branches to page 19.
8A	**Protocol Violation/Deviation - Corrective Action Plan** * Outline what will be done to prevent future occurrences.	Branches to page 19.
9A	**Unanticipated Problem** * Report Type: o Initial Report o Follow-up Report	
9B	* Was there a death in an interventional study for which a Rutgers IRB is the IRB of record that occurred within 30 days of the research intervention? o Yes o No	
9C	* Indicate whether this is an internal or external event: o an internal event o an external event (experienced by subjects enrolled at other institutions)	In an internal event, branch to 11. If an external event, branch to 10.
10A	**Unanticipated Problem - External Event** * Is Rutgers either the IRB of Record for the study or the coordinating center for a multicenter study? o Yes o No	Continue to page 11.
11A	**Unanticipated Problem - Criteria for submission** * Unanticipated Problem Criteria: ❖ unexpected in terms of nature, severity or frequency, given the research protocol, investigator's brochure, IRB-approved informed consent document, product labeling and other sources of information, and given the characteristics of the subject	Multi-select If options 1-3 are not selected and the user selects option 4, branch to page 12.

	population being studied (expected natural progression of subjects' disease, disorder or condition or predisposing risk factor profiles)? ❖ related or possibly related to participation in the research, i.e., is there a definite or reasonable possibility that the incident, experience or outcome may have been caused by the research drug/device or research procedures? ❖ potentially place the research subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized? This includes, but is not limited to, "serious adverse events" ❖ none of the above	If any of options 1-3 are all selected, branch page 13.
12A	**Based upon your responses, the event does not need to be reported to the IRB Office. Only those incidents, experiences, outcomes or adverse events that meet all three of previous criteria need to be reported.** **<u>ALL</u> deaths in interventional studies occurring within 30 days of the intervention when a Rutgers IRB is the IRB of record must be reported.** **Select continue to be redirected to** **Section 1: Reportable Event Information** **You will then have the option to select "Acknowledgement Request" as the submission type.**	Branch to page 2.
13A	**Unanticipated Problem** * Type of report (check all that apply) ❖ Adverse event or injury (Report only if serious, unexpected, and related.) ❖ Adverse device effect (Report only if unanticipated.) ❖ Breach of confidentiality (e.g., lost laptop or mobile device); ❖ Data and Safety Monitoring Board (DSMB) report, interim analysis, or other oversight committee/monitoring report (Report information/minutes, especially if altering the risk/benefit profile.) ❖ Event requiring prompt reporting (Report only when required by the protocol, sponsor, or funding agency.) ❖ New information (Report information indicating an unexpected change in risks or potential benefits, e.g., literature/scientific report or other published finding.) ❖ Subject or Family Member complaint (Report complaints indicating unanticipated risks) ❖ Other problem or finding (e.g., an unqualified subject was allowed to participate on project, loss of study data, a subject becomes a prisoner while participating in research) – specify:	Multi-select For Adverse event or injury, branch to page 14. For Adverse device effect, branch to page 14. For all other selections, branch to page 15.
14A	**Unanticipated Problem - Analysis and evaluation of event** * For the event being reported, provide a detailed description (include location, treatment, outcome and whether subject is still on study):	
14B	* Provide an explanation of why the event is unexpected in terms of nature, severity or frequency:	
14C	* Provide an explanation of how the event is related or possibly related to participation in the research:	
14D	* Provide an explanation of how the event potentially places the research subjects or others at greater risk of harm than previously known or recognized:	Continue to page 15.

15A	**Unanticipated Problem - Research Status** Research Status: • The research participant(s) involved is/are: • Still in study • No longer in study • N/A or unknown	
15B	Research recruitment (in Rutgers research at a site under an Rutgers IRB's jurisdiction) is: • Ongoing • Temporarily Stopped/Placed on Hold • Completed	
15C	Research interventions/interactions involving other participants are: • Ongoing • Temporarily Stopped • Completed for all participants	
15D	**Unanticipated Problem - Notification of subjects** * Will subjects be notified. • Yes • No	If Yes, branch to 16. If No, branch to 17.
16	If yes, please describe:	Branch to 18.
17	If no, please provide justification: **NOTE:** A request for modification will be required to incorporate any proposed communication to subjects.	Continue to 18.
18	**Unanticipated Problem : Corrective Action Plan** Actions To Be Taken: **NOTE:** A request for modification may be required to incorporate changes outlined in your corrective action plan.	
18	**Unanticipated Problem: Reporting requirements** * Describe/Explain compliance to reporting requirements:	
18	Indicate to whom this report (unanticipated problem or adverse event) has been reported to:' and add the following selection • Sponsor	

	• Collaborating investigators • Privacy Officer (if involving protected health information); • Office of the Chief Information Officer (if security incident involving restricted data); • No other reporting or unknown; • Other – specify:	
18	Upload sponsor and/or FDA reports and communications. Document	
19	**Additional Supporting Information** If applicable, upload any other documents that have not been specified in previous questions, but are needed for IRB Review.	
19	If there is any additional information that you wish to communicate about the study please include it below.	
20	**Summary:** **Submission Type:** **Submission ID:** **Next Steps:** **<u>Submit event for IRB review:</u>** For **Protocol Deviations/Violations** and **Unanticipated Problems**, your reportable event application form **<u>will not</u>** be submitted for review until the Principal Investigator returns to the reportable event "workspace," and clicks on "**Submit Report**". For **Acknowledge Requests** and **DSMB reports**, any previously listed study team member can click on "submit report". You can track the status of this study's submission by logging into the study workspace. **<u>To submit:</u>** • Ensure that you have answered all questions in the application and all sections are error-free • Click **Finish**" to exit the application and return to the "**workspace**" • Navigate to the left of your screen, and under "**My Activities**," click "**Submit Report**" to initiate IRB review **<u>Note:</u> A Modification request** will be required if changes to the approved study or documents are outlined in this report.	