**Reporting Undesirable SBS Research Events Form**

* **The Reporting Undesirable Research Events form (RUSRE form) goes through a series of questions that will help you to determine if you need to submit the form and what information you need to provide the KABU-ERC Board. Please refer to the** [**definitions**](http://www.virginia.edu/vpr/irb/sbs/maintaining_defintions.html) **in the** [**Undesirable Events**](http://www.virginia.edu/vpr/irb/sbs/maintaining_unexpected.html) **section of our website in order to answer the questions accurately. If you have questions about this form and/or reporting an undesirable event, please consult our website or** [**contact**](http://www.virginia.edu/vpr/irb/sbs/contact.html) **our office.**
* **The series of questions should help you to determine if it is necessary to report the incident to our office. If you determine that you need to submit the form, please submit the form within 7 days of the incident.**
* **To submit the document, you can email a scanned version to** email **mail P.O Private Bag-20157, or submit directly to our office. Our office will review the form and advise regarding your next steps, which may include submitting a modification to your protocol/consent forms.**

**Protocol Information:**

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| KABU-ERC Protocol Number: |  |
| Protocol Title: |  |
| Principal Investigator: |  |

**Describe the event:** Provide a detailed account of the undesirable event including information about the number of participants involved, what happened, the harm that occurred (if any), how the incident diverged from the protocol, and any steps you may have taken to mitigate the situation.

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**Question Tree**

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| 1. Does the event fit the definition of an adverse event? | Yes |  | No |  |
| *If* ***yes****, answer* ***a****; if* ***no,*** *skip to* ***2.*** | | | | |
| 1. Is the event unexpected? | Yes |  | No |  |
| *If* ***yes****, answer* ***i****; if* ***no,*** *skip to* ***b.*** | | | | |
| 1. Is the event serious? | Yes |  | No |  |
| *If* ***yes****, answer* ***ii****; if* ***no****, skip to* ***d*** | | | | |
| **ii**. Is the event occurring at a significantly higher frequency and/or severity than previously predicted? | Yes |  | No |  |
| *If* ***yes,******submit this report****. If* ***no****, skip to* ***d****.* | | | | |
| 1. Is the event serious? | Yes |  | No |  |
| *If* ***yes****, answer* ***c****; if* ***no,*** *skip to* ***d****.* | | | | |
| 1. Is the event related or possibly related to the research study? | Yes |  | No |  |
| *If yes,* ***submit this report****; if no, continue to* ***d****.* | | | | |
| 1. Does the event alter the level of risk to participants? | Yes |  | No |  |
| *If* ***yes or no****, continue to* ***e****.* | | | | |
| 1. Does the event require you to alter the protocol and/or consent forms? | Yes |  | No |  |
| *If you answered* ***yes*** *to d and/or e,* ***submit this form****. If you said* ***no*** *to both, continue to* ***2****.* | | | | |
| 1. Does the event fit the definition of non compliance? | Yes |  | No |  |
| *If you answered yes to 2,* ***submit this form****. If you said no,* ***file this form for your records****.* | | | | |

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| **Signature of Principal Investigator** |  | **Date** |
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| **Signature of Faculty Advisor (if applicable)** |  | **Date** |