



## Submitting an Unanticipated/Adverse Events Form to Bloomsburg University IRB for review

1) Go to <https://bloomsburg.my.irbmanager.com>

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SteamPunk (2017.11.945.0/Release/b76e137)  
TP-WEB01 at 2019-02-18 16:40:26Z  
Page generated in 0.003 seconds.


2) If you do not have a login account please follow the instructions for a New User Form.

5) Enter the study # that you wish to amend and click find.

Open Items in the next 60 days

6.) Once you are in the study, please click “start x-form” under actions in the upper left corner.

The screenshot shows the IRB Manager interface for a study titled "Study 2018-150-BU Research (IRB)". On the left-hand side, there is a vertical menu under the heading "Actions". The "Study" section is expanded, and a red arrow points to the "Start xForm" option. The main content area displays details for the study, including the study number (2018-150), committee (BUIRB), category (Office of Research and Sponsored Programs), department, agent types (Focus Groups), study title (Expedited Test), and review type (Expedited). Below this, the "Study-Site" section shows the site name (BU Research - BU Research) and PI (Hauck, Sadie). At the bottom, an "Events (1)" table shows a "New Submission" event on 12/20/2018 with 5 attachments and reviewer Sadie H.

7.) If you wish to see all of the questions on this form, click “printer icon”  and this will give you a copy of the form that is easily printed.

8) If you wish to fill out this form, choose the blue link for the **“Unanticipated Problems.”**

The screenshot shows the "Start xForm" page in the IRB Manager. It features a table titled "Select xForm to start" with columns for "Action", "Form (Click to start)", and "Description". A red arrow points to the "Unanticipated Problems" form in the list. The table contains the following information:

Action	Form (Click to start)	Description
	Continuing Review of Research	This form is used for continuing research that was initially approved by either an expedited or a full review by the BUIRB. This request must be submitted at least yearly and three weeks PRIOR to the anniversary of the previous approval so that continuing approval may be received.
	IRB Application Form (1/1/19)	Use this form for all new proposals submitted to the BUIRB regardless of what category you expect the Proposal to fall under.
	Key Personnel Change Form	Use this form if you are submitting any modification(s) to the previously approved key research personnel, including any additions or deletions of personnel, any role or duty changes, or any changes in any personnel qualifications (i.e., CV, resume or training certificates).
	Modification to Protocol Form	Use this form to notify the IRB of any changes to your previously approved research. Do not use this form for changes to personnel - Use the Key Personnel Change form for those changes.
	New Contact Submission	Please provide contact information for everyone involved in this study.
	Post Common Rule - Continuing Review of Research	This form is used for continuing research that was initially approved by either an expedited or a full review by the BUIRB. This request must be submitted at least yearly and three weeks PRIOR to the anniversary of the previous approval so that continuing approval may be received.
	Study Closure Final Report	Please use this form when your study is complete (all participant data is collected and analyze, all interventions are complete, no follow-up interventions are taking place, and enrollment is closed).
	Unanticipated Problems	Please complete this form for any adverse or unanticipated problems that occur during the course of a study.

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9) Please answer all pertinent questions.

https://bloomsburg.myirbmanager.com/Forms/FormPage.aspx?FormInstanceStageGUID=97d0eca4-cc53-4fb2-96b4-052982446a0

Study 2018-150-BU Research (L...) xform - Unanticipated Prob...

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Collaborators Unanticipated Problem Header Page 1 of 2

**Bloomsburg UNIVERSITY**

Unanticipated Problems -- Unanticipated Problem Header

<b>Submitter</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
Email: _____ Business: 570-389-4322		
<b>Protocol Title</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
Expedited Test		
<b>Protocol Number</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
2018-150		
<b>PI</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
Email: _____ Business: 570-389-4208		
<b>Faculty Advisor</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
N/A		
<b>Date of Incident (Required)</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		
<b>Summary of Incident (Required)</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		

https://bloomsburg.myirbmanager.com/Forms/FormPage.aspx?FormInstanceGUID=be3654fc-b213-48e8-819a-c742cf6e0b66&FormPageGUID=90da78d5-a202-42aa-9030-5d17

Study 2018-150-BU Research (L...) xform - Unanticipated Prob...

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Collaborators Event Details Page 2 of 2

**Bloomsburg UNIVERSITY**

Unanticipated Problems -- Event Details

<b>Causes (Required)</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		
<b>Actions or Response (Required)</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		
<b>Do you plan to submit an amendment (Required)</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="checkbox"/>		
<b>Change in Safety Plan (Required)</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="checkbox"/>		

8) Enter your changes to the study.

9) Once you've completed and submitted the form, BUIRB Administrator will begin the review process.