

Post Approval Submission: Unanticipated problem

The screenshot displays the IRBIS web application interface. The top navigation bar includes the IRBIS logo, the text 'Office of Human Research Ethics', and a 'Logged in as D...' indicator. A menu bar contains links for HOME, ADMIN, GENERAL MANAGEMENT, HELP, and LOGOUT. The main content area is titled '>> Report of Unanticipated Problem' and includes a 'Help' link. The form displays the following information:

IRB Number:	08-0800	Study Status:	Approved
PI:	David Tegnell	IRB:	Behavioral
Sponsor:			
Study Title:	Human Resource Factors Related to Organizational Growth in Peruvian Microfinance Institutions		
Reference ID:	0		

Below this information is a section titled '>> Brief Description of Unanticipated Problem'. It contains a red warning message: 'The brief description is limited to 200 characters.' followed by a text input field. Below the input field is explanatory text: 'The next few questions will help determine if this event needs to be reported. Reportability is defined by federal guidance. If the event is determined to be reportable, you will have the option of uploading any supporting documentation at the end of the submission process. If you fail to press the 'Submit' button at the end of this event submission, your report will not be forwarded to the IRB.' This is followed by another question: 'Does this report apply to any other of your studies? If so, please select below.' with a dropdown menu and a search icon. At the bottom of the form is a '>> Next' button.

Unlike other post approval submissions, unanticipated problems are reported outside the IRB application. The online UP/AE report is unchanged from that implemented June 1, 2009. See the OHRE website for additional information and specific training materials:

<http://research.unc.edu/offices/human-research-ethics/online-submission/unanticipated-adverse/index.htm>