

IRB Protocol Violation Reporting Form

The IRB is responsible to review reported protocol violations involving human subjects and may request appropriate measures be taken to rectify the violation to ensure that the violation does not reoccur.

The UK IRB defines and categorizes protocol violations in two categories;

- Protocol Exceptions
- Protocol Deviations

according to the following definitions:

Protocol Exception

*The enrollment of a research subject in a protocol that fails to meet protocol inclusion criteria or a person who should **not** have been enrolled based on protocol exclusion criteria.*

Examples:

- enrolling a 70 year old patient when the inclusion criteria specifies 25-65 years of age.
- enrolling a patient with serious disease that is precluded from participation in the protocol exclusion criteria.

Protocol Deviation

A departure from the protocol for a research subject once that subject has actually been satisfactorily enrolled.

Examples:

- drawing a 13th tube of blood from a subject where the protocol specifies that 12 samples will be collected for the study
- instituting a procedure on one or more enrolled subjects that is not specified in the protocol.

If any of the above should occur *without prior IRB approval* in an active IRB protocol, complete the information on page 2 and submit to: IRBSubmission@uky.edu

This Report Form must be submitted to the IRB within 14 days of the occurrence.

IRB Protocol Violation Reporting Form			
PI Name:		IRB Protocol #:	
Title of Study:			

Date: _____

<u>ADMINISTRATIVE INFORMATION</u>	
P.I. Signature:	
P.I. Telephone Number:	
P.I. E-mail Address:	
Date of Protocol Violation:	
Project is extramurally funded:	Yes No
If yes, list agency(ies):	
Reporter name:	
Reporter Telephone number:	
Reporter E-mail address:	
Nature of the protocol violation : (whether a protocol exception or deviation)	
Describe the subsequent action taken, if applicable:	
If the violation involved a prisoner subject, provide the following information:	<p>Was the prisoner a patient in the University of Kentucky (UK) hospital/medical center at the time of the violation? Yes No</p> <p>If the prisoner was not a patient in the UK hospital/medical center, describe how the study physician was involved in the care during the critical incident or follow-up to the violation:</p>