



Human Research Protection  
Program Institutional Review  
Board Procedure

PROCESS FOR FOLLOW-UP TO  
QA/QI REVIEW

DESCRIPTION

The HRPP auditing staff will ensure that the IRB Chairperson is notified of the results of each study review conducted to ensure that potential or actual continuing or serious noncompliance is identified and addressed by the Board.

RESPONSIBILITY

The Human Research Auditor, IRB Chairperson and the Human Protections Administrators will ensure that all activities regarding the quality assurance and improvement review is carried out in order to provide adequate notice and information to the parties involved.

PROCESS

1. Based on the recommendations listed in the site visit report, the HRPP Director or designee will determine whether or not corrective action response from the PI is necessary. If no corrective action response is necessary the finalized site visit report will be sent to the PI with notification of the determination. A copy of the finalized site visit will be sent to the IRB Chairperson or designee for review.
2. If a corrective action response is necessary, then the HRPP Director or designee will send the finalized site visit report to the PI with notification of the determination and a request for a response to the site visit report recommendations. A copy of the finalized site visit and the PI's responses to the site visit report recommendations will be sent to the IRB Chairperson or designee for review.
3. The HRPP Human Research Auditor in conjunction with the IRB will verify that the PI's submitted responses to the site visit report recommendations contain adequate corrective and preventative measures.
4. The Board will be notified of all completed site visits. If findings indicate non-compliance, then an investigation will be conducted per UC Human Research Protection Research Policy VII.03.
5. If the Board determines additional review is required, the auditing staff will be asked to perform a follow-up review to determine if the deficiencies were corrected and report the findings to the PI, the IRB Chairperson and the Director of UCORI.



**Procedure Number: 325**

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**Adopted: 04/2007**

**Revised: 06/2014**

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6. The IRB will review the follow-up site visit report and determine if further actions are required per UC IRB Procedures and UC Human Research Protection Program Policies.

**IRB FILE FINDINGS**

1. If any IRB procedural problems were identified during the review, a report detailing these will be sent to the HRPP Director or designee. The HRPP Director will take action to correct any procedural problems identified.

*Applicable Regulations, Document(s):*

Policy # VII.01 "Quality Improvement Activities in Human Research Protection"

Policy # VII.03 "Investigating Allegations of Non-Compliance in Human Subjects Research"

*Additional Documents:*

Not Applicable

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
04/2007	M. Linke & J. Lindwall	07/2007	J. Lindwall	Updated the PAMP activity with the PI responses to the site visit report.
		09/2010	A. Braggs-Brown	Updated IRB Office and Chairperson activity with the site visit reports. Minor clarifications in language.
		01/2011	A. Braggs-Brown	Updated IRB Office and Chairperson activity with the site visit reports. Minor clarifications in language.
		05/2014	A. Braggs-Brown	Revised to reflect organizational changes

**Date June 2014**

**Signature signed copy on file**