Ethics Committee, Research Committee. UANL School of Medicine	SOP:FOLLOW-UP OF COMPLAINTS, SUGGESTIONS OR COMMENTS			
	Number	Date	Author	Approved by
	QA 903-A **Ver3**	1-01-2011	I. Hernandez, V. Gómez, J. Garza	J. G. Gonzalez

I. PURPOSE

I.1. Describe the process of quality control for follow-up of complaints, suggestions or comments.

I.2. Starts with the respection of a complaint, suggestion or comment.

I.3. Ends when the complaint, suggestion or comment is resolved or terminated

II. REVIEW OF PREVIOUS VERSIONS

None

III. POLICIES

Quality assurance (QA) and quality control (QC) in the processes of review and monitoring of complaints, suggestions or comments are the cornerstone of the research subjects protection program because it is a direct link between the participant and us.

Specific policies

1.1 The follow-up of complaints, suggestions or comments serve as part of the process of finding strengths and weaknesses in our program; in this way our quality control program ensures the follow-up of these observations through a standardized process.

The Secretary of Clinical Research through the Quality Control coordination reports to the Office of the Vice Dean of Research the observations, follow-up and finally, its end, ensuring that there is compliance with the internal quality control program. If necessary, our processes can be modified according to the observations from these complaints, suggestions or comments.

IV. RESPONSIBILITIES

The Secretary of Research as the individual responsible for the HRPP, through the Coordination of Quality Control are responsible for the implementation of this procedure; this in order to follow-up these observations.

He/she is also responsible for implementing the QA/QC corrective actions to our operating procedures if any are needed.

V. SCOPE

These policies and procedures apply to all aspects of the Ethics, Research, and Biosafety Committee.

V. PROCEDURE

Describes the procedures that assist the management of the Ethics, Research, and Biosafety Committee to maintain and ensure the effectiveness of the Quality Control Program with regard to follow-up of complaints, suggestions or comments.

Who	Task	Tool
Secretary of Clinical Research	Reviews complaints, suggestions or comments received through our call center or website.	QA 903-A
Quality Control Coordinator	Receives complaints, suggestions or comments through QA 903-A from the assistant who received it.	
Assistant Secretary	As soon as he/she receives the complaint, comment or suggestion, informs the Quality Control Coordinator, so that he/she can, together with the Secretary of Clinical Research, provide follow-up using the same form.	
Vice Dean of Research	Receives a monthly report of complaints, suggestions or comments	
Secretary of Clinical Research	Makes changes to the operating processes of the program after review by the members, requesting approval from the Vice Dean of	

	Research.	

VI. MATERIALS

QA 903-A COMPLAINT, SUGGESTION OR COMMENT FORM

VII. LINKS OF INTEREST OR DOWNLOADS

VII.1 45 CRF 46
http://ohsr.od.nih.gov/guidelines/45cfr46.html#46.103

VIII. REFERENCES

1. 45 CFR 46.116(a)(6)-(7)
2. AAHRPP Reference. Element I.4.A, I.5.C

COMPLAINT, SUGGESTION OR COMMENT FORM

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Date Received	
Person who file complaint, suggestion	**Anonymous** **Name:**
Type of communication:	**Complaint** **Suggestion** **Comment**
Linked Study	**Not applicable** **Title of the study**
Researcher involved:	**NA** **Name:**
Registration Number	**NA** **Number**
Department/Service involved:	
Complaint, Suggestion or Comment	**Describe:**
Contact telephone,address or email:	**Anonymous** **Contact data:**

FOLLOW-UP

Date	Follow-up notes	Name of the person who does the follow-up:

Was it necessary to modify the SOP, internal regulation, or another internal document?	N◯ Y◯:_____ _____
Observations	
Name and Signature of the Coordinator of Quality Control	
Name and Signature of the Secretary of Clinical Research	