RUTGERS UNIVERSITY
Office for Research

FORM: Complaint Or Allegation Intake Form		
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Instructions: Staff may use this form to document receipt of a complaint about research or allegation of non-compliance. Once completed, notify the HRPP IRB Director or QA&E Director for direction.

Your name: _____ Date/ Time of Receipt: _____

COMPLAINANT CONTACT INFORMATION [Leave blank if anonymity requested**]:**

Name : _____

Address: _____

Telephone :_____Email: _____

Do they permit us to reveal their identity as the source of this complaint or allegation to the study's Principal Investigator or other study staff? ___ Yes ___ No

Are they reporting this complaint or allegation for someone else? ___ Yes ___ No

If yes, please explain: _____

STUDY INFORMATION:

Instructions: If the complaint/allegation refers to a specific study or study staff, please obtain and record that information here.

Protocol Name: _____ IRB PRO # _____

Study Staff Name(s): **Role in Research:**

_____ _____ _____

_____ _____

Is or was the complainant a participant in this study? ___ Yes ___ No

If yes, when did they start and end participation the study? _____

Did they contact the PI or study staff about their complaint or allegation? ___ Yes ___ No

If yes, who did they contact and when?

Study Staff Name(s) **Date Contacted:**

_____ _____

DESCRIPTION OF COMPLAINT OR ALLEGATION

Instruction: Please describe in detail the complaint or allegation**.**

OTHER/CLOSURE WITH COMPLAINANT

How would they like to see their complaint or allegation resolved?

Is there anything else we can help them with?

Can a Human Research Protection Program QA&E Team member contact you for additional information if needed?

YES _____ NO_____

If Yes, Preferred email _____ if Yes, Preferred phone number_____

Closing Script for individual speaking with complainant:

In our effort to respect the privacy and confidentiality of all parties involved, it is our policy not to share the details of the outcome of our reviews. Please be assured that the Human Research Protection Program and the Institutional Review Board fully investigate and resolve all issues that come to our attention.

If the complainant describes any risks or harms as a result of the research study, ask whether the subject has seen a health provider/physician? If yes, document as much information as can be obtained about the risks/harms and care that was obtained (i.e., name of health care system, name of physician, dates risks/harms occurred, dates care was provided). Inform the subject that someone will call them back to follow-up on their concerns. Inform the IRB Chair and QA&E Director promptly after the call.