**Instructions:** Staff may use this form to document receipt of a complaint about research or allegation of non-compliance. Once completed, notify the IRB Asst Director or HSPP Executive 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 Subject Protection Auditor 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 Subjects 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 HSPP Executive Director promptly after the call.*