

**Syracuse University**

**Office of Research Integrity & Protections**

**IRB #:**

**Title:**

**Principal Investigator:**

**CITI Training:** [ ]  Current [ ]  Not Current

**Date of Audit:**

**Site of Audit:**

**Review Level:** [ ]  Exempt [ ]  Expedited [ ]  Full Board

**List all other Co-Investigators/Key Personnel on the project:**

|  |  |  |
| --- | --- | --- |
| Name | Role | CITI Certification |
|       |       | [ ]  Current [ ]  Not Current |
|       |       | [ ]  Current [ ]  Not Current |
|       |       | [ ]  Current [ ]  Not Current |
|       |       | [ ]  Current [ ]  Not Current |
|       |       | [ ]  Current [ ]  Not Current |

**Others:**

**Original Approval Date:**

**Last Renewal Date:**

**Expiration Date:**

**# of Subjects Approved:**

**# of Subjects Enrolled:**

**# of Subjects Withdrawn:**

**Consent Process:**

Was a written Consent Form required?

[ ]  Yes [ ]  No [ ]  N/A

If required, was an IRB approved/stamped Consent Form available, signed, and dated by each subject?

[ ]  Yes [ ]  No [ ]  N/A

If required, was it the correct approved/stamped version? (Check Expiration Date)

[ ]  Yes [ ]  No [ ]  N/A

Was a verbal consent process required (not written)?

[ ]  Yes [ ]  No [ ]  N/A

If verbal, was the approved script used?

[ ]  Yes [ ]  No [ ]  N/A

Was an other type of consent process required/approved?

[ ]  Yes [ ]  No [ ]  N/A

If other, was the IRB approved process followed and documented?

[ ]  Yes [ ]  No [ ]  N/A

Comments:

**Eligibility:** *All inclusion/exclusion criteria listed within the protocol should be carefully checked including age, gender, race, any vulnerable populations, etc.* **Explain any deficiencies found:**

If any deficiencies/deviations were found, were they reported to the IRB in a timely manner?

[ ]  Yes [ ]  No [ ]  N/A

All subjects were eligible?

[ ]  Yes [ ]  No [ ]  N/A

Comments:

**Recruitment:**

Did the recruitment process follow the IRB approved protocol?

[ ]  Yes [ ]  No [ ]  N/A

Did the advertisement materials match those approved?

[ ]  Yes [ ]  No [ ]  N/A

Comments:

**Unanticipated Problems:** *Review all unanticipated problems claimed, reviewed, and verified.* **Explain any deficiencies found:**

Are unanticipated problems recorded in the research records?

[ ]  Yes [ ]  No [ ]  N/A

Was the SU IRB notified of unanticipated problems?

[ ]  Yes [ ]  No [ ]  N/A

Are complaints recorded in the research records?

[ ]  Yes [ ]  No [ ]  N/A

Was the SU IRB notified of complaints?

[ ]  Yes [ ]  No [ ]  N/A

Did the investigator respond to the complaints?

[ ]  Yes [ ]  No [ ]  N/A

Comments:

**Recordkeeping/Security:**

Were the records legible and organized?

[ ]  Yes [ ]  No [ ]  N/A

Did electronic data match the paper records?

[ ]  Yes [ ]  No [ ]  N/A

Was all required and necessary information provided?

[ ]  Yes [ ]  No [ ]  N/A

Were security measures in place to protect privacy and confidentiality (locked, coded, etc.)

[ ]  Yes [ ]  No [ ]  N/A

Did security measures follow the approved protocol?

[ ]  Yes [ ]  No [ ]  N/A

Comments:

Additional information regarding this Audit:

Audit reported and reviewed by the SU Director of ORIP.

[ ]  Yes [ ]  No [ ]  N/A

Comments:

ORIP Director Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This Audit will be presented to the Convened IRB on Meeting Date:

Auditor Name (Print):

Auditor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Auditor Name (Print):

Auditor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Others involved with this Audit: