Tulane University Human Research Protection Program
Investigator Self-Assessment Checklist
For Exempt, Expedited, or Convened IRB Protocols

**Purpose:**

The purpose of this checklist is to provide guidance to research staff, assist investigative staff in self-monitoring and ensure compliance with the Tulane University IRB and federal policies.

The components listed are part of the routine compliance audit conducted by the Tulane IRB.

There may be protocol-specific additional requirements.

For further information, please contact the Tulane IRB at (504) 988-2665 or the Research Compliance Officer at (504) 988-1147.

Principal Investigator:  IRB #:  Date:

Title:

**Approval and Record Keeping:**

The project has current IRB approval.

☐ Yes  ☐ No  ☐ N/A

All research personnel involved with the project are currently certified in CITI Human Subjects Protection Training.

☐ Yes  ☐ No  ☐ N/A

All applicable personnel involved with this project have completed all COI requirements (CITI COI, Tulane University Attestation forms, etc.)?

☐ Yes  ☐ No  ☐ N/A

Investigator files contain the following IRB documentation:

*NOTE: All records must be kept for at least 3 years after completion of the research.*

☐ Protocol (all versions)
☐ Initial Approval Letter for Initial Protocol with original Informed Consent

☐ Amendment Approvals with approved Informed Consent (if applicable)

☐ Signed Informed Consent Forms (originals) for enrolled subjects (If kept in a subject shadow chart, then a note to file in the regulatory binder stating such)

☐ Continuing Review Approvals (if applicable)

☐ Adverse Events (if applicable)

☐ Any other important IRB Correspondence

☐ Any sponsor provided correspondence

Were there any changes to the approved project since the last Continuing Review?

☐ Yes  ☐ No  ☐ N/A

If Yes, was an Amendment submitted to the IRB? ☐ Yes  ☐ No  ☐ N/A

Have there been any changes to Application Part I (study personnel, study locations, etc)?

☐ Yes  ☐ No  ☐ N/A

Corrective Actions for Approval and Record Keeping:

Subject Consent Forms (if applicable):

Are personnel who are obtaining consent forms from subjects are authorized and trained to obtain consent for this study?

☐ Yes  ☐ No  ☐ N/A

Was the IRB approved/stamped version of the consent/assent used to enroll subjects?

☐ Yes  ☐ No  ☐ N/A

Were all consent forms signed by subjects prior to enrollment?

☐ Yes  ☐ No  ☐ N/A

If using an oral consent, the IRB approved the script used to enroll subjects?
☐ Yes  ☐ No  ☐ N/A
Did the subject initial each page of the consent form?

☐ Yes  ☐ No  ☐ N/A
Do you have a signed and dated consent form on file for every subject enrolled in the study?

☐ Yes  ☐ No  ☐ N/A
If changes were made to the consent form, were the changes submitted and approved by the IRB?

Corrective Actions for the Subject Consent Forms:

Recruitment of Subjects:

Subjects were identified and recruited according to the methods approved by the IRB?

☐ Yes  ☐ No  ☐ N/A
Any advertising or recruitment materials used to recruit subjects were approved by the IRB prior to implementation?

☐ Yes  ☐ No  ☐ N/A
All inclusion/exclusion criteria listed and approved by the IRB were followed?

☐ Yes  ☐ No  ☐ N/A
Any deviations were reported to the IRB?

☐ Yes  ☐ No  ☐ N/A
If subjects received any compensation for participation, is there documentation?

☐ Yes  ☐ No  ☐ N/A
Corrective Actions for the Recruitment of Subjects:

Research Protocol:

Issued: 9/24/09  Last Reviewed: 9/6/17
Effective: 9/24/09  Last Revised : 9/13/13
Form #: 201
Research conducted complies with the project description and procedures as approved by the IRB?

☐ Yes  ☐ No  ☐ N/A

All data collection instruments used were approved by the IRB, prior to implementation?

☐ Yes  ☐ No  ☐ N/A

**Corrective Actions for the Research Protocol:**

**Privacy, Data Storage, and Confidentiality:**

The subject’s privacy is protected and safeguards are in place as approved by the IRB?

☐ Yes  ☐ No  ☐ N/A

If you proposed to collect the data anonymously, has anonymity been maintained in the physical or electronic records?

☐ Yes  ☐ No  ☐ N/A

Are hard copies (consent forms and data forms) stored in a secure, locked location?

☐ Yes  ☐ No  ☐ N/A

Is electronic data on a secure and protected computer?

☐ Yes  ☐ No  ☐ N/A

Are electronic data files password protected?

☐ Yes  ☐ No  ☐ N/A

Is access to computer, electronic files, and physical files limited to appropriate personnel?

☐ Yes  ☐ No  ☐ N/A

Was the research data (raw) stored/disposed of as described and approved by the IRB?

☐ Yes  ☐ No  ☐ N/A

**Corrective Actions for Privacy, Data Storage, and Confidentiality:**
Continuing Review:

Are you aware of when your project expires?

☐ Yes  ☐ No  ☐ N/A

Are you aware of the IRB Submission Deadline date for the Continuing Review of your project?

☐ Yes  ☐ No  ☐ N/A

Have there been any lapses in IRB approval? If Yes, did you report any research activity that was completed during the lapse?

☐ Yes  ☐ No  ☐ N/A

Have there been any Adverse Events or Unanticipated Problems, complaints, or subject withdrawals while conducting this research? If Yes, have all details been reported to the IRB?

☐ Yes  ☐ No  ☐ N/A

Have there been any new findings to change the risk benefit ratio?

☐ Yes  ☐ No  ☐ N/A

Corrective Actions for Continuing Review:

Pharmaceuticals:

If you are an investigator using an investigational new drug (IND) or an investigational device exemption (IDE), do you have:

☐ A Monitoring Plan in place for routine review of research records?

☐ A Form FDA 1572 (IND only)?

☐ N/A

Are you using proper procedure for drug accountability (Receipt of the study product, dispensing, return, terminal disposition of product, etc.)?

☐ Yes  ☐ No  ☐ N/A

Corrective Action for Pharmaceuticals:
Study Closure: If your project is complete, fill out the Study Closure Form on the Tulane IRB Website to close the protocol.

Other Corrective Actions: