

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

**Effective Date of
Closure or
Suspension:**

Reason for Closure or Suspension

Please list reason for closure or suspension:

Subject Accrual

	Since the last IRB Review	Since Initial Approval of study
Number of subjects who signed a consent form (enrolled) or number of records reviewed if a chart review study		
Number of potentially vulnerable subjects* enrolled: (*Children; pregnant women; fetuses; neonates; cognitively impaired adults; adults medically unable to consent; non-English speaking subjects; employee of PPMH or a PPMH facility; educationally / economically disadvantaged; terminally ill (life expectancy < 3 months)		
Number of consented subjects who voluntarily withdrew		
Number of consented subjects who are lost to contact / follow-up		
Number of consented subjects who were withdrawn by the Investigator		
Number of consented subjects who have completed the study		

**Study Progress – Internal / Local Events
“Events” – SAEs, IND Safety Reports, MedWatch Reports, Deviations, Violations**

Number of internal / local events reported to date:

Number of internal / local deaths reported to date:

Have all internal / local events / deaths been reported to the IRB?

Yes

No

If **NO**, explain:

Attach any internal / local events not previously reported.

**Study Progress – External / Non-Local Events
“Events” – SAEs, IND Safety Reports, MedWatch Reports, Deviations, Violations**

Number of external / non-local events reported to date:

Have all external / non-local events been reported to the IRB?

Yes

No

If **NO**, explain:

Attach any external / non-local events not previously reported.

Study Findings

Have there been any significant new findings (good or bad) that should be disclosed to subjects who participated in this study?

Yes

No

If **YES**, attach a narrative regarding the new findings and any plans for informing subjects.

Principal Investigator Acknowledgement

I attest that the information contained herein is a true and accurate representation of my ongoing study.

P.I.'s Name: _____ Date: _____

Electronic Signature:

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

**IRB Review of Protocol Closure or Suspension
(Completed by IRB Office Only)**

Date of Receipt: _____

Determination:

The protocol closure or suspension report has been reviewed by the IRB and no further action is required.

The protocol closure or suspension report has been reviewed by the IRB and additional information is being requested. See attached memo.

Full Board Review Date: _____