

## Minor Deviations Tracking Log

**Protocol deviations** are any deviation from the IRB-approved protocol that are not approved prospectively by the IRB. **Major protocol deviations** are deviations from the IRB approved protocol that "has the potential to negatively impact subject safety, the integrity of study data or subject's willingness to participate in the study". **Minor protocol deviations** are deviations that do not have the potential to negatively impact subjects, their willingness to participate or data integrity. **Minor deviations include**, but are not limited to, protocol deviations such as out of window visits, missing tests/labs, missing original/signed consent form (copy exists), missing PI signature on consent form(s), use of expired/outdated consent form that includes all relevant information, over-enrollment, failure to submit continuing review prior to expiration of IRB approval.

**Instructions:** This log is to be used for tracking and reporting minor deviations according to Reporting Unapproved Deviations in PHRC-Approved Research policy: [http://healthcare.partners.org/phsirb/Guidance/Reporting\\_Unapproved\\_Deviations\\_in\\_PHRC-Approved\\_Research.1.11.pdf](http://healthcare.partners.org/phsirb/Guidance/Reporting_Unapproved_Deviations_in_PHRC-Approved_Research.1.11.pdf). Minor deviations are to be reported **ONLY** at continuing review. **NOTE: Entries in the log must be typed.**

<b>PI:</b>							
<b>Protocol #</b>							
<b>Title:</b>							
<b>Sponsor:</b>							
Date Deviation Discovered	Date Deviation Occurred	Subject Study ID	Description of Deviation	Description of Corrective Action	Date Sponsor Notified	Date Sponsor Approved	Recorded by / Date