HENRY J. AUSTIN™
HEALTH CENTER
The center for wellness

PROTOCOL DEVIATIONS/VIOLATIONS EVALUATION FORM

Use this form to report protocol deviations or violations that occur at your site.

PROJECT INFORMATION		
IRB Protocol Number:	Date of Submission:	
Title of IRB-Approved Protocol:		
Principal Investigator Name:	Sponsor:	Sponsor Protocol Number:
Study Drug(s)/Device(s) [if applicable]:	Subject ID(s):	

Nature of Deviation: Describe the deviation(s)/violation(s), including date(s):
Did deviation(s)/violation(s) affect subject safety? ☐ YES ☐ NO *If yes, please provide an explanation of why the deviation/violation occurred and the outcome.
Was sponsor notified? ☐ YES ☐ NO If yes, please provide date, documentation and Sponsor's response If no, why not?
Outline your corrective action plan to prevent future occurrences.

Please provide a copy of the IRB approved protocol and the IRB approved informed consent, if applicable.

- *If applicable, p*lease complete the "additional documentation or attachments form" appended at the end of this form to include and include a copy of *IRB approved protocol and the IRB approved informed consent* **(Use upload forms function at the bottom of this webpage.)**

Principal Investigator (Print Name) Date

Principal Investigator Signature