

Form-6 Amendment to Study

Do not use this form when submitting revisions requested by the IRB.
Submit IRB-requested revisions under a separate cover letter.

IRB #:

Date of Amendment:

Principal Investigator:

Service/Department:

Co-Investigator(s):

Study Title:

Sponsor:

This amendment contains (check all that apply):

New	Revised	Informed Consent Form
New	Revised	Protocol
New	Revised	Supplementary Materials

Submit a copy with Tracked Changes of any revisions to approved documents, and/or a clean copy of any new documents.

Please list all documents being added or amended, using Version Number and/or Version Date, if applicable:

How many subjects are currently enrolled at Wills?

Does this amendment change the risk to benefit ratio of the study in any way?

YES

NO

Please explain:

Are changes to the current approved informed consent form required?

YES

NO

Please explain:

Contact Information

Telephone:

Email:

Name of Individual Completing this Report

As Principal Investigator, I have read all materials included in this amendment and submitted to the IRB.

Signature of Principal Investigator

Date

Instructions: Complete all required fields and submit signed form to IRB@willseye.org with all required documentation.