OBJECTIVE
The objective of this guidance is to define the procedure for the administrative check-in of protocols as part of IRB-SBS requirements for investigators.

RESPONSIBILITY
IRB staff members and the post-approval monitor will be responsible for the administrative check-in procedure and follow-up.

PROCEDURE
All protocols that do not have a requirement for continuing review will undergo an annual administrative check-in.

The Principal Investigator will receive a notice one year after project approval to submit a Check-in form, with instructions to submit the form in a timely manner. The check-in will remind PIs of their obligation to submit amendments and event reports, and will enable IRB staff to know if a protocol should be closed.

The Protocol Manager will review the check-in responses, closing projects as appropriate. Protocol issues which require follow-up, such as a need for a modification submission, will be forwarded to the appropriate IRB-SBS staff member. The project will be referred to the post approval monitor if the need for a follow-up assessment is identified.

REFERENCES:
Admin Check-in notification Letter 1-2A
Admin Check-in warning email 1-2B
Study Closure email 1-2C