

5-Year Renewal Guidelines

ALL FORMS ARE AVAILABLE ON THE IRB WEBSITE
(<http://www.upstate.edu/researchadmin/compliance/irb/>)

FIFTH YEAR RENEWAL PROCEDURES

A study may only be renewed 4 times by the continuing review process. After the fourth continuing review, if the study is to continue, it is necessary to re-submit the study as described in section 6 of the IRB guidelines. Although the IRB number will remain the same, all other procedures will be the same as for new protocols.

As part of the re-submission, Question #1 (summary) in the application should include any and all changes and amendments to the study since initial approval. In addition, the following information must be included:

- 1) that this study has been ongoing for 5 years,
- 2) what (if any) problems have there been with the conduct of the study,
- 3) what (if any) changes have there been to the study,
- 4) how many subjects have been enrolled (**if a multi-center study include total enrollment**) and,
- 5) what (if anything) has been learned so far.

A notice that the study has received 4 continuing reviews and needs to be re-submitted will be sent to the Principal Investigator, by mail, at least one month prior to the study expiration date; however, there may be problems with the IRB database which cause a renewal notice not to be issued. Therefore, an investigator should not depend solely on IRB notification as a prompt for submitting a new application.

Under no circumstances may the study proceed without the completion of the review process and approval granted.