Federal regulations and University policy mandate:

- If approval for continuation is not granted prior to the expiration date of the protocol, all recruitment, subject enrollment, and other research related activities (e.g. study visits, chart reviews, data analysis using subject identifiable data, manuscript development, and etc.) must stop.
- Currently enrolled subjects should continue to receive treatment and follow-up that is in their best interest.
- Failure to submit timely requests for continuing review demonstrates non-compliance with federal regulations and institutional policy and is reportable to the FDA, OHRP, and the study sponsor (when applicable).
- Continued non-compliance affects the investigators standing with the IRB and may prohibit the investigator from conducting future research at the University.

IRB office requirements:

- In order to prevent non-compliance due to an expired protocol, an investigator must submit his/her Continuing Review Application or Final Study Report to the IRB office
  - At least 4 weeks in advance of the expiration date of IRB approval for minimal risk (expedited) protocols
  - At least 8 weeks in advance of the expiration date of IRB approval for greater than minimal risk (full board) protocols
- If non-compliance occurs due to an expired protocol, then the investigator must submit the Expired Study Report Form with his/her Continuing Review Application or the Closure Form with his/her Final Study Report. Both forms require the investigator to provide a detailed corrective action plan.

Corrective Action Plan for Expired Protocols

A corrective action plan describes how a delayed submission resulting in an expired protocol will be prevented from occurring in the future and what changes in procedure are being implemented to prevent protocol approvals from expiring in the future.

Below are three examples of acceptable corrective action plans:

Example #1

1. My system/procedure to track deadlines will be by placing the dates in my calendar and in the calendar of the co-investigators and other study personnel.

2. The visual tool, with an available alarm, is the Outlook calendar that we will be using.
3. My plan for maintaining calendar notifications for expiring protocols will be to set an alarm in the calendar which will notify us of expiration dates. The calendar will be backed up on the departmental server in case the local drive fails.

Example #2
The study’s coordinator is going to construct a well-organized e-file system for every study under the PI’s name. The folder will be located on the PI’s shared drive and will be organized by protocol. There will be subfolders within each protocol’s folder, organized in chronological order, for each of the continuing reviews, amendments, and etc. This system will provide anyone new to the study, such as new research fellows, with easy access to the status of all studies under this PI and the most current IRB documents. Additionally, the coordinator is going to develop a spreadsheet for all protocols under the PI. The spreadsheet will be updated as needed and will serve as a quick reference for when continuing reviews need to be compiled and submitted.

Example #3
Upon receiving approval from the IRB:

1. I will complete corrections to the final chapter of the project. At the time of suspending the project all of the research was completed. My faculty advisor had only reviewed the data that I compiled and only made recommendations for corrections to the written report.

2. I will complete those corrections to the written report and then give my faculty advisor a weekly progress update on Fridays.

3. My faculty advisor and co-investigator will review my final written report.

4. I will schedule a weekly meeting in person with my faculty advisor to review her recommendations to the final document.

5. I plan to present the findings and submit the paper for publication. The results of this study will provide evidence based information to the ongoing discussion among stakeholders as they attempt to provide enhanced healthcare for foster children in the State of New Jersey.

6. I will submit a Final Study Report/Study Closure Form to the IRB at least 4 weeks before my IRB approval expires after my paper has been accepted for publication or presentation and no additional analysis of the data will be done. If further data analysis is needed before my paper is accepted, then I will submit a Continuing Review Application to the IRB at least 4 weeks before my IRB approval expires.

Please note that exact duplication of these examples in place of an original corrective action plan will not be accepted by the IRB and will be returned to the investigator to be revised and then resubmitted to the IRB.