[month, day, year]  
[Recipient Name]  
Principal Investigator, IRB-SBS# xxxx  
[Department]  
Dear [Recipient Name]:  

I am writing in follow-up to previous communications regarding your study, IRB-SBS # [            ], entitled “[                   ]”, which requested a completed Self-Assessment Checklist for this study. The following communications have been sent in an attempt to receive a completed Self-Assessment Checklist:

- Initial e-mail, [date], with instructions to submit the checklist by [deadline date #1]
- Reminder e-mail, [date], with instructions to submit the checklist by [deadline date #2]
- Phone call, [date]
- Letter of notification, [date sent] that this protocol is closed to enrollment, with instructions to submit the checklist.

As described in the initial notifications, this study was selected for a Self-Assessment Checklist review as part of the Post Approval Monitoring and Education program (PAM &ED). This program is part of UVA’s commitment to assure human subject safety, provide feedback and education to investigators and their study teams, and identify both strengths and areas needing improvement in research policies and practice at the University of Virginia.

Please note that review of the completed checklist is required by the IRB as part of compliance with the University’s Federal Wide Assurance Agreement and is not considered optional. Since the IRB has not received a Self-Assessment Checklist, it will be necessary to schedule a full on-site assessment with the post approval monitor. This study will be remain closed to enrollment until that review is complete. Please contact Margaret Ball, mnw2h@virginia.edu, as soon as possible to schedule the review of your protocol.

Sincerely,

David J. Hudson, PhD  
Senior Associate Vice President for Research  
Phone: 243-0900  
Email: dhjh2t@virginia.edu

Cc: Research Compliance Monitor  
    IRB-HSR Chair  
    Faculty Advisor

04/15/20