ProTECT™ III Close-out Milestone Activities, Part 2

Protocol Number: Version 7 FDA IND Number: IND #104,188 Sponsor: David W. Wright, MD, FACEP	Hub Name: Spoke(s) Name: Principal Investigator:

Close-out Milestone Activities PART 2 of 2:

This page describes milestones in the second part of the ProTECT close out. This primarily relates to EFIC-required post-trial public disclosure (PD) activities. **Please do NOT initiate activities 3 – 9 on this list until after the ProTECT primary paper has been published**. A menu of suggested PD activities and template language will be made available. You will be able to use these materials to develop your own PD plan and materials. We will also facilitate sharing of materials across sites at that time. All materials will be posted in the ProTECT Toolbox.

End of Study Public Disclosure Activities (EOSPD)	Yes	No	Comment
1. Develop an EOSPD plan for your site and upload the plan to WebDCU. We suggest that the IRB agree with this PD plan before you begin. Upload as regulatory document name: **ProTECT EOS PD Plan**.	☐	☐	
2. Maintain regulatory compliance in WebDCU.	☐	☐	
Payment for Completion of Tasks 1 – 2 *(payment first available following database lock)*			**25% of total payment***
3. Develop local EOSPD materials and send to Deneil (dkolk@umich.edu) for review. If materials will be sent to IRB, they should be reviewed by Deneil **prior** to IRB submission.	☐	☐	
4. IRB must review the EOSPD activities and determine that the EFIC regulatory requirement has been met. Upload documentation** under regulatory document name: **ProTECT EOS PD IRB Acknowledgement.**	☐	☐	
5. Complete **Public Disclosure Summary Forms** after completing each EOSPD activity. There should be a summary form for each unique PD activity completed. Notify Deneil (dkolk@umich.edu) once you have completed all of your PD summary forms for verification. Any queries generated from the verification process must be resolved for this task to be complete.	☐	☐	
6. Maintain regulatory compliance until end of study activities.	☐	☐	
7. Inform IRB of final study close out – following conclusion of PD events.	☐	☐	
8. Upload documentation of IRB approval of final study close out in WebDCU under: **ProTECT IRB Close-out Acknowledgement**.	☐	☐	
9. Obtain PI signature on final Delegation of Authority log. Once all study team members are made inactive in the Project Spoke Team Member table and end dates are added to the Delegation of Authority log, please upload into WebDCU.	☐	☐	
Payment for Completion of Tasks 3 - 9			**25% of total payment***

**Sample language for IRB acknowledgment statement:

"Per 21 CFR 50.24 (a)(7)(iii), The IRB has found and documented the ProTECT trial end of study public disclosure to contain sufficient information needed to apprise the community and researchers of the study about: the demographic characteristic of the research population and it's results."

*Total Close-Out Milestone payments (Part 1 and 2) to each hub will be as follows:

$30,000 per Hub with at least 1 subject enrolled
$10,000 per additional Spoke with at least 1 subject enrolled