ProTECT™ III Close-out Milestone Activities – Part 1

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

Please note that this milestone document is for use at Spokes that enrolled ProTECT Subjects. For those Spokes that were active but did not enroll a ProTECT Subject, please reference the ProTECT Close-out Milestone Activities for Spokes with No Subject Enrollments document.

Close-out Milestone Activities PART 1 of 2:

A. Immediate Actions	✓	Comment
1. Continue to remain active, following all study subjects through end of study.	☐	
2. Submit the Trial Sponsor's **Closing to Enrollment letter** (dated November 4, 2013) to all IRBs of Record within 2 weeks of receipt of the letter, or by November 18, 2013.	☐	
3. Submit the **NIH Official Letter** addressed to the Trial Sponsor (dated October 30, 2013) to all IRBs of Record by November 18, 2013.	☐	
4. Submit the **ProTECT III Subject Notification Letter** for IRB approval by November 18, 2013. Upload the letter and documentation of IRB approval in the NETT Regulatory Database (WebDCU) under document entry: ProTECT IRB Approved Subject EOS Notification Letter.	☐	
5. Distribute the ProTECT III Subject EOS Notification Letter to all subjects via registered US mail within 2 weeks of IRB approval. Following this, provide attestation of distribution to all subjects in WebDCU.	☐	
6. Dispose of all remaining study drug per local guidelines, document kit destruction in drug accountability binder, and reconcile in the ProTECT Database (WebDCU) by February 4, 2014. Please retain the box tops for each destroyed kit for verification at the final monitoring visit.	☐	

B. Data Collection, CRF Completion, and Monitoring Action Items	✓	Comment
Quickly finishing data collection and achieving data base lock is important to providing timely payments, will allow more rapid analysis and publication, and will allow us to return to post-trial public disclosure as quickly as possible. We are counting on everyone rapidly and accurately finishing data collection.		
1. Obtain/prepare source documents for review at final monitoring visit.	☐	
2. Ensure that all BIO-ProTECT blood samples have been shipped to Banyan Biomarkers, Inc., as per the BIO-ProTECT manual by December 13, 2013.	☐	
3. Ensure that head CTs/MRIs have been shipped to Emory or submitted electronically within 2 weeks of discharge for all subjects.	☐	
4. Ensure that all 6 month outcome videos and worksheets have been sent to Emory (as applicable) within 30 days of the final End of Study visit for all active subjects.	☐	

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5. Complete and close all notification and informed consent processes that are outstanding (obtaining signed and dated IRB approved Informed Consent Documents by Subject or LAR, or notification only as approved by NETT Operations Committee).	☐	
6. Document and report all AE/PAAE/SAEs that have not yet been reported. Update and submit all SAEs that required follow-up. Respond to all outstanding DCRs for more information on PAAE/SAEs within 24 hours.	☐	
7. Complete all required CRF data in the ProTECT Database and submit CRFs as per the CRF Completion Guidelines. *Data Entry Timeframes:* Daily Checklist and Daily Transgression Forms – by midnight for the previous 24 hour period. Baseline through End of Study CRFs – within 5 days, except where noted PAAE/SAEs – within 24 hours of first knowledge of the event	☐	
8. Resolve all open Data Clarification Requests (DCRs) within 5 days of query generation (or within 24 hours for PAAE/SAEs).	☐	
9. Ensure an Investigator has reviewed and signed off on CRF pages requiring signature.	☐	
10. Resolve all Monitoring Action Items in the ProTECT eMonitoring module within 30 days of the final monitoring visit.	☐	
11. Ensure an Investigator has reviewed all monitoring reports from 2013-2014 and has completed the "PI Affirmation" section of the eMonitoring module within 30 days of the final monitoring visit.	☐	
12. Ensure all CAPA plans are closed out locally and resolved within the eMonitoring module within 30 days of the final monitoring visit.	☐	
13. Data enter all CC events conducted through November 3, 2013 into the WebDCU ProTECT Database on their own Community Consultation Summary Form. Notify Deneil (dkolk@umich.edu) once you have completed all of your CC summary forms for verification. Any queries generated from the verification process must be resolved for this task to be complete.	☐	
14. Data enter all PD events conducted through November 3, 2013 into the WebDCU ProTECT Database on their own Public Disclosure Summary Form. 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.	☐	

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C. Regulatory Document Requirements	✓	**Comment**
1. Maintain continuing IRB approval, with documentation of continuing approval uploaded into WebDCU under: ProTECT Protocol v7 IRB Approval.	☐	
2. Maintain current Delegation of Authority Log in WebDCU.	☐	
3. Monitor Log (upload to WebDCU after final monitoring visit).	☐	
4. Subject ID code list (Master subject log) and signed consent forms are maintained at site (NOT in WebDCU), but must be available for monitoring.	☐	
5. Maintain regulatory compliance (required documents up to date in WebDCU) until the study has ended completely (final database lock, end of public disclosure, study closed with IRB).	☐	

D. Study Supplies	✓	**Comment**
1. Dispose of all remaining unused BIO-ProTECT supplies as per local guidelines.	☐	

Close-out Milestone 1 **Payment to conduct end of study PD activities** **(contingent upon completion and approval of close-out tasks outlined in part 1 of 2)**	50% of total payment*

***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)