

General Information	Comments
WVURC or WVU	
Principal Investigator	
Sponsor/CRO	
Site agreement	
Protocol Number	
Period of Performance	
Termination	
<u>Termination by Institution:</u>	
Does the Institution have the right to terminate in the event of an adverse event?	
Does the Institution have the right to terminate if the safety & health of patients are compromised?	
Does the Institution have the right to terminate in the event of a material breach by Sponsor?	
Does the Institution have the right to terminate if the IRB and/or FDA withdraws approval of the study?	
Does the Institution have the right to terminate without cause?	
If the PI leaves the Institution, can Institution negotiate for replacement pre-termination?	
<u>Termination by Sponsor:</u>	
If Sponsor terminates for material breach, does Institution have the right to cure the breach?	
<u>Payment upon Termination:</u>	
Does the Institution have the right to prorate payment based on work performed prior to termination?	
Will the Institution be reimbursed for costs irrevocably committed?	
Confidentiality	
Is the disclosing party required to mark confidential information as such?	
Does the definition of Confidential Information preclude publication rights?	
Are the five exceptions to confidential information included?	

Is a Nondisclosure/Confidentiality Agreement required or referenced?	
Publication	
Is Sponsor's written approval required prior to publication?	
Is Sponsor's review and comment required prior to publication?	
Does Institution have the right to retain copyright to publications resulting from Agreement?	
Disclaimer required in publications - views expressed are not necessarily endorsed by sponsor	
Are we allowed to acknowledge the existence of the Agreement?	
Inspections	
Does the Sponsor have the right to respond to regulatory correspondence?	
Intellectual Property	
WVU and Sponsor jointly own all rights to data, materials, etc.	
Sponsor owns all rights to data, materials, etc.	
WVU owns all rights to data, materials, etc.	
Does Institution have the right to use IP for internal, educational research purposes?	
Data	
Does Institution have the right to use data for internal, educational research and patient treatment purposes?	
Does Institution have the right to retain data or other information for archival purposes?	
Budget	
Is the final budget attached to the Agreement?	
Reference Material	

Animal Care and Use Guidelines	
Guidelines of the Institutional Review Board for the Protection of Human Research Subjects	
OMB Circular A-110 incorporated into this award	
OMB Circular A-133 incorporated into this award	
OMB Circular A-21 incorporated into this award	
Policy and Procedures for Responding to Allegation of Misconduct in Research and Scholarship at WVU	
Security	
Certificate/assessment completed. No Plan required	
Export Control Plan required	
Foreign Nationals participation restricted	
Sponsor Required Approvals	
PI change requires sponsor's prior approval	
Key personnel change requires sponsor's prior approval	
Sponsor's prior approval required if PI expected to be away from project for more than 3 months	
Governing Law	
Does the agreement specify governing law?	
Does the agreement specify jurisdiction?	
Does the agreement specify venue?	
Insurance	
Is our insurance coverage properly stated?	
Indemnification	
Does Sponsor agree to indemnify?	
Do we agree to indemnify?	
Is a Letter of Indemnification required?	
Alternative Dispute Resolution	
Does the agreement require binding arbitration or mediation, or non-binding arbitration?	

AAHRPP	
Does the agreement include the Institution's preferred AAHRPP language?	
Warranties	
Is there a disclaimer by Sponsor and if so, has mitigating language been added?	