To: [PI_NAME]  
[DEPARTMENT]  

From: [IRB]  

Date: [NOW]  
Expiration Date of Approval by External IRB: [EXPIRATION_DATE]  
RE: Agreement to Rely on External IRB  
External Organization: [EXTERNAL_ORG]  
Study #: [IRB_ID]  
[NON-IRB_COMMITTEES]  
Study Title: [TITLE]  
[SPONSOR_PROTOCOLS]  

This confirms that an IRB Authorization Agreement with the organization identified above has been executed to rely on their IRB for continuing oversight of this study. This agreement specifies the roles and responsibilities of the respective entities.  

[DESCRIPTION]  

[SUBMISSION_DESCRIPTION]  

[FINDINGS]  

It is your responsibility to:  

1. Inform the UNC-CH IRB about any actions by the external IRB affecting their approval to conduct the study, including suspension or termination of approval.  

2. Report all determinations (by the IRB of record) of UPIRSO, Serious Noncompliance or Continuing Noncompliance involving UNC subjects or researchers, and Suspension or Termination of IRB approval of research within 14 calendar days of notification. You may submit a copy of the report you submitted to the external IRB; this should be done via the IRBIS UP reporting pathway.  

3. Maintain compliance with all other UNC-CH policies (e.g., data security, Investigational Drug Service [IDS], conflict of interest).  

4. MODIFICATIONS: Submit the following modifications to the UNC-CH IRB (via IRBIS):  
   a. The addition of new study personnel  
   b. A change in Principal Investigator  
   c. The study is modified in such a way that additional institutional approvals are required (e.g., radiation safety, biosafety, COI).  
   d. The Sponsor/CRO has modified the subject injury language in the consent documents.  It is your responsibility to confirm that that subject injury language has not been modified without the appropriate changes to the CTA.  

5. RENEWALS: Submit a copy of the external IRB approval letter and if the study remains open to enrollment, a copy of the current MAIN parental permission or adult consent document to the UNC-CH IRB (via IRBIS). You will continue to receive reminder notices from the UNC-CH IRB. You should provide approval and current consent documents within 30 days of approval by the reviewing IRB.  

Do not submit materials other than those requested above.  

In addition, you should provide a copy of this letter to [EXTERNAL_ORG] or CRO, if they registered on your behalf.  

[CC]