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. Submit a modification to the UNC-CH IRB (via IRBIS) if/when new personnel are added to the study team or the study is modified in such a way that additional institutional approvals are required (e.g., radiation safety, biosafety).

3. Submit a copy of the external IRB approval letter and current approved consent document to the UNC-CH IRB (via IRBIS) when the study is renewed; you will continue to receive reminder notices from the UNC-CH IRB for renewal, and should provide the external approval and consent documents within 30 days of receipt.

4. Report all Unanticipated Problems protocol violations and unresolved subject complaints to the UNC-CH IRB *in addition to the external IRB.* You may submit a copy of the report you submitted to the external IRB; this should be done via the IRBIS UP reporting pathway.

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

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

[CC]