**Required Elements in a Letter of Amendment**

Date:

Re: Letter of Amendment for [insert Protocol Number, Version, dated \_\_\_\_\_\_\_ ]

Title: [Insert title]

To:

From:

The following information impacts the [*insert Protocol Number*] study and must be forwarded to your Institutional Review Board (IRB)/Ethics Committee (EC) as soon as possible for their information and review. This must be approved by your IRB/EC before implementation.

The following information may also impact the sample informed consent. Your IRB/EC will be responsible for determining the process of informing subjects of the contents of this letter of amendment.

Upon receiving final IRB/EC and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. Sites are still required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. An LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with this letter and any IRB/EC correspondence should be retained in the site’s regulatory files.

* List out the changes to the protocol

The above information will be incorporated into the next version of the protocol at a later time if it is amended.