To: DAIDS-sponsored and/or supported Clinical Research Sites and Operations Centers

From: Jui Shah, Ph.D., DAIDS RSC Contracting Officer's Representative (COR)

Date: January 18, 2017

RE: **Lists of IND and non-IND protocols having Case Report Forms (CRFs) and Pharmacy Records that will not be stored by DAIDS**

The DAIDS Regulatory Support Center (RSC) website provides "Lists of IND and non-IND protocols having Case Report Forms (CRFs) and Pharmacy Records that will not be stored by DAIDS". The Division of AIDS (DAIDS) has determined that the documents associated with these studies no longer require storage and may be destroyed in accordance with investigator's institutional policies.

Documents from studies that are not included in these lists must be stored in accordance with local institutional policy or may be transferred to the DAIDS RSC for long-term storage, upon authorization by DAIDS, if requested by the Principal Investigator or their designee. Note that only CRFs and pharmacy records (except for participant prescriptions) may be shipped to the DAIDS RSC for long-term storage. Alternatively, sites may choose to continue to store CRFs and pharmacy records for these studies.

The Principal Investigator is responsible for submitting the request for authorization to ship CRFs and pharmacy records to the DAIDS RSC, as described in the Instructions document that is also posted on the DAIDS RSC website under the Clinical Research Sites tab on the CRF Management page (https://rsc.niaid.nih.gov/clinical-research-sites/case-report-form-management). Upon approval by DAIDS and shipment of the CRFs and pharmacy records from the sites, the DAIDS RSC is responsible for receiving and repacking these documents for transfer to long-term storage. The Instructions document posted on the DAIDS RSC website outlines the processes for receiving DAIDS approval and the transfer of the CRFs and pharmacy records. Any questions regarding this process should be addressed to the DAIDS RSC CRF Coordination Team at crf@tech-res.com.