[Institutional Review Board (IRB) or Ethics Committee (EC) Lead Person (if applicable)]

[IRB/EC Name]

[IRB/EC Street Address]

[IRB/EC City, State, Country]

[Date]

Re: Request to review [Clinical Research Site (CRS) Name, CRS Number] Standard Operating Procedure (SOP) on Co-enrollment Prevention for Clinical Studies

Dear [Enter name of IRB/EC/appropriate institutional review body],

Our Clinical Research Site (CRS) conducts clinical trials sponsored by the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID). DAIDS, as the sponsor, has instituted a new requirement that all clinical research sites participating in DAIDS-sponsored clinical trials within the DAIDS Clinical Trial Networks develop and implement a Standard Operating Procedure (SOP) describing how the site will address identifying and preventing participant co-enrollment in our studies based on study specific requirements. The requirements and additional resources may be found on the DAIDS Clinical Research Policies and Standard Procedures Documents website within in the SCORE Manual at the following location: [<https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations>]

DAIDS has instituted this requirement to strengthen site compliance with International Council for Harmonization/ Good Clinical Practice (ICH/GCP) guidelines and the United States (U.S.) Code of Federal Regulations (CFR) relating to the protection of human subjects in clinical trials. Identifying and preventing inappropriate co-enrollment will help maintain participant safety and ensure the integrity of clinical trial data. The following regulations and guidelines have been considered in developing this new requirement:

* U.S. Department of Health and Human Services (HHS) regulations for the Protection of Human Subjects at 45 CFR 46
* World Medical Association Declaration of Helsinki adopted in June 1964
* Food and Drug Administration (FDA) regulations on Protection of Human Subjects at 21 CFR 50
* International Conference on Council for Harmonization (ICH) Good Clinical Practice guidelines (ICH E6).

DAIDS is requiring that sites submit their SOP to their local IRB/EC for review and approval. Obtaining IRB/EC approval helps to ensure that the procedures are within the context of local laws and regulations and acceptable to local populations. We [CRS name] reviewed the mentioned regulations, as well as the local, in country regulations [add applicable local regulation], and developed the attached SOP [SOP Name] to comply with this requirement and implement a robust internal process to maintain participant safety and ensure integrity of clinical trial data.

Your timely review and approval are very much appreciated. Although this type of review may not be in your normal purview, we appreciate your consideration.

Sincerely,

[CRS Leader Name]

[CRS Name/Number]

[CRS Address]

[CRS Leader phone number]

[CRS Leader email]