Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual Appendix:

Clinical Research Site Guidance for Developing a Co-Enrollment Prevention Standard Operating Procedure

Clinical Research Sites (CRSs) must have a Co-Enrollment Prevention SOP in place as detailed in the Co-Enrollment Prevention Section of the SCORE manual. The following guidance is intended to help CRS staff in developing the SOP.

Each SOP includes the following details about the site's plan for co-enrollment prevention:

1. A description of the risk analysis that is done to identify potential sources of co-enrollment, and the frequency that the risk assessment is completed. See the next section for examples of questions that sites can ask themselves to assess risk of co-enrollment at the site. The site is to also consider any gaps in the co-enrollment prevention plan and describe the plan to mitigate the associated risk.
2. The process for obtaining co-enrollment information and how information is disseminated about possible contraindicated clinical trials being conducted within the same recruitment area.
3. The procedures which are used to determine whether potential participants within the recruitment area have screened or enrolled at multiple sites, and the frequency that these procedures are performed.
4. Measures taken by the CRS for adjudication and resolution of identified cases of prohibited co-enrollment.
5. Which CRS staff members (by role) conduct the co-enrollment identification and prevention procedures and where CRS staff document the results.
6. The type of system (i.e., manual, electronic or computerized systems) used to identify and prevent co-enrollment. *Note*: Electronic or computerized systems, where available, are preferred to manual processes. Computerized co-enrollment systems should be evaluated based on the [DAIDS Electronic Information Systems (EIS) Policy](#).
7. For electronic co-enrollment systems, the alternate procedure that will be followed if the system is temporarily unavailable (e.g., power outage, no internet access).
8. How the co-enrollment system allows the sharing of certain data between the participating sites while still protecting the participants' PII.
9. How the CRS communicates enrollments with other DAIDS CRSs (and non-DAIDS sites when appropriate and when allowed by local regulatory authorities). This will include details on the frequency of the communication, documentation of information, and a plan to address confidentiality and privacy.
10. Details on disclosure of co-enrollment process in the informed consent form (ICF) of each participating study (as required by the institution's IRB/EC).
11. How and when the institutional review board/ethics committee (IRB/EC) and any other reviewing committee is informed about the co-enrollment identification and prevention procedures and all approval requirements.

Risk assessment. When developing the site SOP for co-enrollment prevention, and considering the level of risk at the site, consider the following questions and also add any additional questions that may be relevant to the site and regional area.

1. Is the site conducting multiple protocols?
2. Is the site conducting more than 1 protocol which is enrolling the same participant population?
   The greater the number of protocols a site is conducting, the more likely it is that participants could try to co-enroll. This is especially true if those protocols target the same population or involve an investigational product. The risk of co-enrollment is also present at sites conducting additional research studies that are not DAIDS funded or are not HIV related.

3. Is the site enrolling HIV prevention trials?
   If yes, this is a higher risk – co-enrollment has most often been identified in HIV prevention trials.

4. Has the site previously identified a co-enrollment or co-enrollment attempt at the site?
   If yes, then it is highly likely that site will see more attempts.

5. Is the site aware of another research site within a 25 mile/ 40-kilometer radius that is conducting HIV/AIDS clinical research whether or not funded by DAIDS?
   If yes, and especially if those sites are conducting the same studies or studies with similar population or investigational product, then the likelihood is higher that the site will see co-enrollments. Sites are encouraged to engage other DAIDS and non-DAIDS sites in the geographic region in their co-enrollment prevention plan as much as possible. Also consider the frequency that site staff will coordinate with other sites before enrolling new participants.

6. Is the site located in a densely populated area?
   If yes, the risk of co-enrollment is higher than that in more rural areas, or areas with less public transportation.

7. Yes or no: The site doesn't currently have a system to detect co-enrollment.
   If the site does not have any system, that means a higher risk of a co-enrollment, because the site is not actively looking for co-enrollments. If a site already has a manual or automated system in place, the risk is lowered, but probably not zero. More automated systems or biometric systems are the most effective, but even a manual system will mitigate the risk of co-enrollment.

The more questions that have a "yes" response, the higher the level of co-enrollment risk at the site. The level of risk will also vary based on other specifics at the site. For instance, a site with 10 protocols will have more risk than a site with 2 protocols, and less risk than a site with 30 protocols.

If the risk of co-enrollment is low, and no co-enrollment prevention process or system is needed, the CRS is still required to develop the co-enrollment prevention SOP showing that the risk assessment has been performed and documented, and the risk is reassessed on an ongoing basis.

If the site self-assesses the risk of co-enrollment as high, DAIDS recommends that the site put in place a co-enrollment detection and prevention system. Although automated, biometric, electronic systems are usually very effective and therefore preferred, the system can be manual, or sites can use a simple spreadsheet or database. The system used should be described in the site SOP.