*[Insert Institution Letterhead]*

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

[Enter IRB/EC Name]

[Enter IRB/EC Street Address]

[Enter IRB/EC City, State, Country]

[Enter Date]

**Re: Request to review [Enter Clinical Research Site (CRS) Name, CRS Number] Standard Operating Procedure (SOP) on Age & Identity Verification**

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 Institutes of Allergy and Infectious Disease (NIAID). DAIDS, as the sponsor, has instituted a new requirement that instructs all clinical research sites participating in DAIDS-sponsored clinical research within the DAIDS Clinical Trials Networks to develop and implement a standard operating procedure (SOP) describing how the site will verify participants’ age and identity before they take part in a clinical trial and at each subsequent visit throughout the study. The requirements and additional resources may be found in the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual at the following location: [https://www.niaid.nih.gov/research/daids-score-manual](https://urldefense.com/v3/__https:/www.niaid.nih.gov/research/daids-score-manual__;!!May37g!c3pZOLjZT6pBA1OEFyHAca0uIO6-i8QPFNncF7ozTpfHiQYLUftbyccRBGzDQ9oF$)

DAIDS has instituted this requirement to strengthen site compliance with International Council for Harmonisation/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. Verifying the age and identity of participants will help maintain their 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 part 46
  + U.S. Food and Drug Administration (FDA) regulations on Protection of Human Subjects at 21 CFR part 50
  + FDA regulations on Investigational New Drug Application at 21 CFR part 312
  + International Council for Harmonisation (ICH) Good Clinical Practice guidelines (ICH E6).
  + FDA regulations on Institutional Review Boards at 21 CFR part 56

DAIDS has requested that sites submit their SOP to the local IRB/EC for review and approval. Although many sites now also use single IRB for certain studies, obtaining local IRB/EC approval of this SOP 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 [ Enter SOP Name] to comply with this request 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.

Sincerely,

[Enter CRS Leader Name]

[Enter CRS Name/Number]

[Enter CRS Address]

[Enter CRS Leader phone number]

[Enter CRS Leader email]