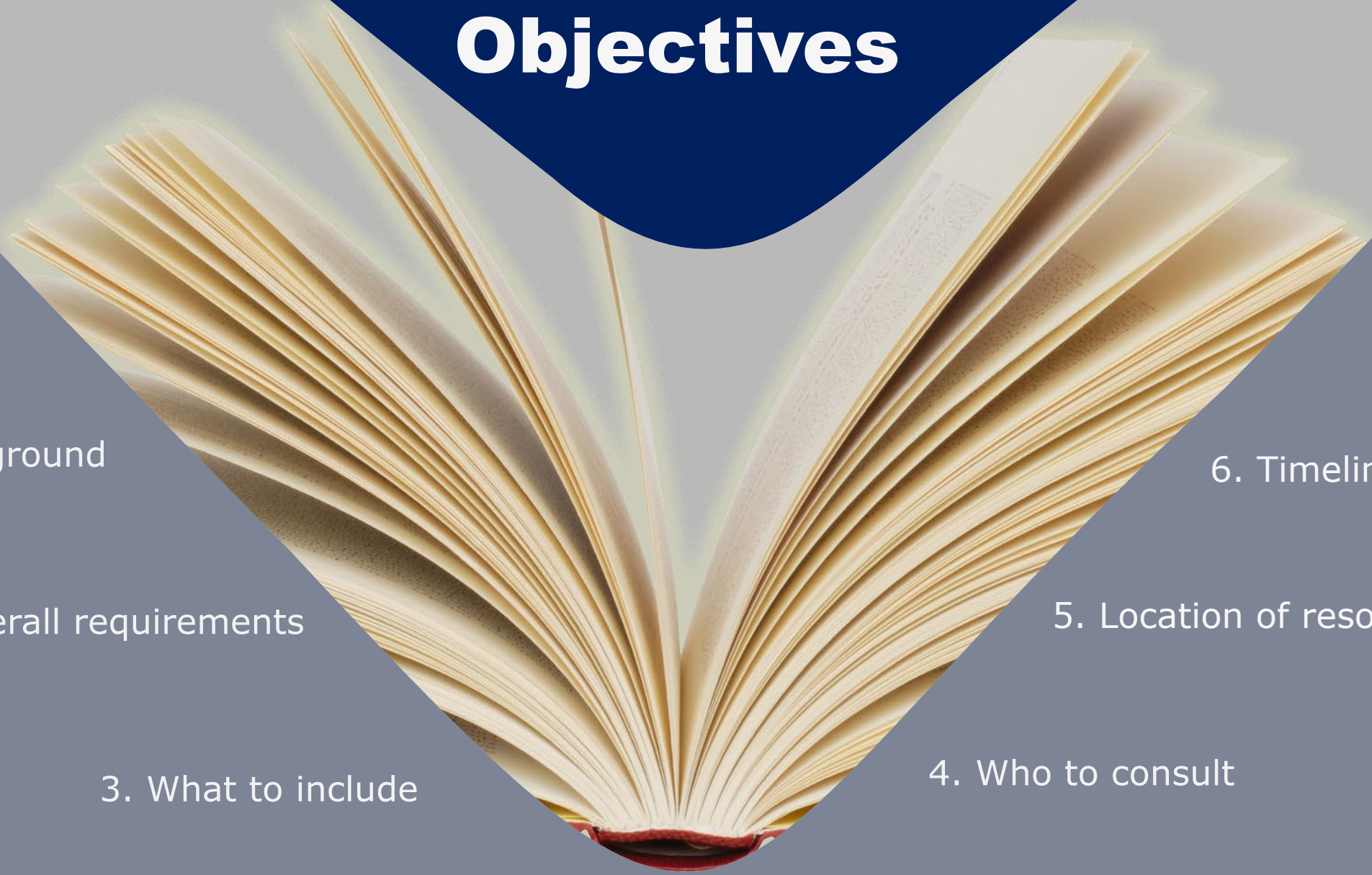
National Institute of Allergy and Infectious Diseases

Co-Enrollment Prevention Requirement Update

Sept 28, 2021

The DAIDS SCORE MANUAL
Site Clinical Operations and Research Essentials

Objectives



1. Background
2. Overall requirements
3. What to include
4. Who to consult
5. Location of resources
6. Timelines

Background

- Co-enrollment prevention policy development first began in 2018
- Why was a policy needed?
  - Result of regulatory inspection findings of deficiencies in site procedures on Age & Identity Verification (A&I) and Co-enrollment Prevention (CEP)
  - Experience with prohibited co-enrollments at DAIDS CRSs in the US and abroad
- A&I Verification requirement developed first and implemented in SCORE manual January 2021.
- Timeline for both policies delayed several times due to complexity of the issues and efforts to address feedback from stakeholders.

Outreach Efforts on CEP

- 2018 – 2019: Calls with other NIH groups, Network leadership, site staff, and community representatives to discuss co-enrollment systems.
- 2019 – 2020: Consultation with HIPAA SME for development of HIPAA FAQ
- June to September 2021: Policy updates to Network LOCs, HANC Cross Network SC group, HANC Community Partners

Co-enrollment: What is it and why should we prevent it?

- What is co-enrollment?
  - Co-enrollment is enrollment of a participant in more than one clinical trial or in the same trial at multiple locations. For the purposes of this requirement, it refers to co-enrollment that is prohibited by the eligibility criteria of a protocol.

- Why is it important?
  - Participant safety concerns due to:
    - Exposure to more than one study product and the potential drug interactions
    - Exceeding blood volume limits imposed by American Red Cross or country requirements.
  - Difficulty assessing causality of AEs
  - Impact to study data integrity and approval of study product for licensure
  - Potential for unblinding of studies/participants

CEP Requirements

- All CRSs conducting DAIDS sponsored research within the DAIDS Clinical Trials Networks must have an SOP describing their co-enrollment prevention process.
- Each site will review local laws and regulations and assess their risk level for co-enrollment to determine the methods to be implemented.
- Each site will submit Site SOP to local IRB/EC or other relevant institutional group for review and approval before implementation.
- The SOP and documentation of IRB/EC decision should be maintained in site files, available to DAIDS monitors for review.

What to Include in Site SOP

- Self Assessment of Risk – Use questions from the guidance document and add your own
  - Describe how the assessment will be performed and the results
- Based on the risk assessment, describe what kind of procedures you will put in place to identify and prevent co-enrollment
  - What type of system will you use? (Manual, electronic, automated, etc.)
  - Will you partner with other sites in the area?
  - What information will you collect? How will you determine co-enrollment and share information with other sites in the area?
  - How will sensitive data be protected?
  - Who will conduct the procedures?
  - How will participants be notified? Will the details of the process be included in the ICF?
  - How and where will results of the CEP checks be documented?
  - How and when will the IRB/EC be informed of the procedures?
  - When and for what reasons will the risk assessment be repeated in the future?
- How will the site handle any identified cases of prohibited co-enrollment?

You’ve found a co-enrollment – now what?

- Notify protocol team, OCSO PO, IRB/EC immediately
- Report as a significant protocol deviation
- Work with the protocol team and OCSO PO to determine next steps
- Conduct a root cause analysis and adjust your SOP as necessary

Who to Consult for SOP Development

- CAB and Community – Consulting with these groups will ensure that methods in the SOP will work for all stakeholders and can be implemented smoothly.

- Local IRB/EC – Submit the SOP to a local regulatory review body to make sure that they are aware of the procedure and that it conforms with local laws, customs and considerations.

- Other institutional groups involved with participant safety - Consult with these groups throughout the SOP development process to strengthen the procedure. Such groups may include office of research integrity, institutional ethics office, human research protections office, etc. If the IRB/EC will not review the SOP, please try to seek out one of these groups to review instead.

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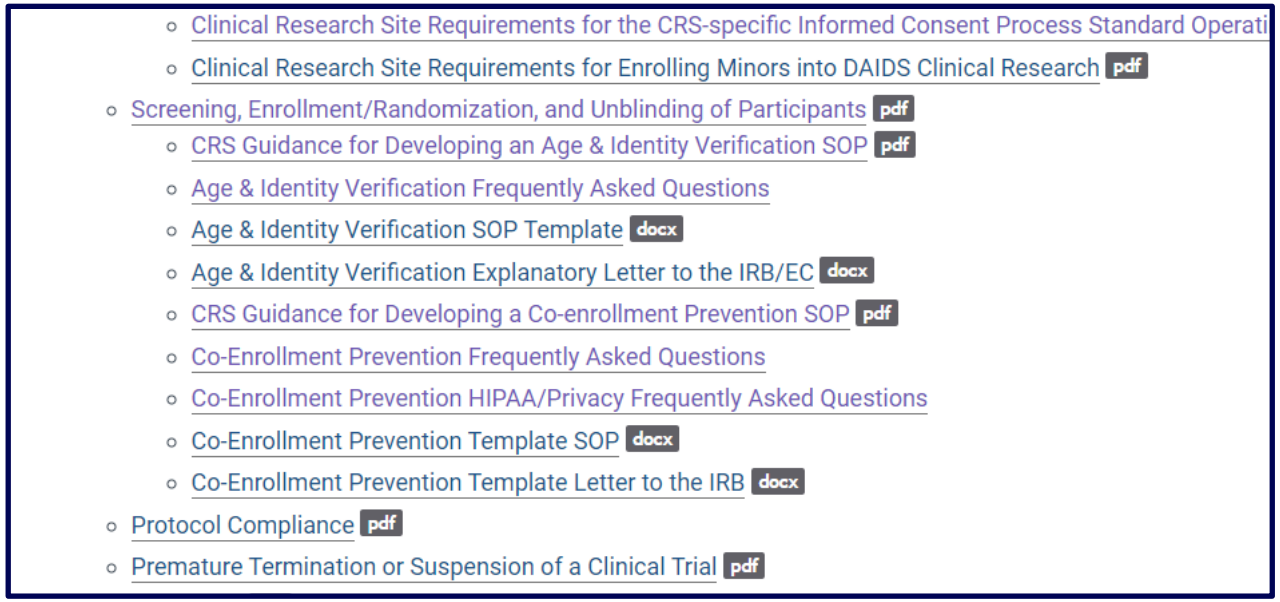
Location of Resources

Included in SCORE manual with the Age & Identity Verification requirement.
(Screening, Enrollment, Unblinding section)

Appendices:

- Guidance document
  - Things to consider/include in SOP
  - Risk assessment guidance
- SOP template (optional)
- Template letter to the IRB/EC (optional)
- FAQ
- HIPAA FAQ



Timeline and Next Steps

- September 20 – New documents available in the SCORE manual
- September 28 – Webinar (video to be posted to the HANC portal)
- October 1 – December 31, 2021 – Sites develop the SOP and get approval from their IRB/EC
- January 1, 2022 – SOP should be in effect
- 2022 TBD – Monitors to start looking for presence of SOPs and approval documentation.

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Questions?