Dear US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet) Affiliate Organization (AO),

This document serves as an example that you as the study site PI may follow when organizing the regulatory files for your IND and/or Non-IND Study Site Binder (SSB), per ICH/GCP E6 Section 8. The checklist within this document includes the documents applicable to most IND and Non-IND studies per ICH/GCP. However, **this checklist will need to be modified by each AO** based on each protocol’s regulatory requirements, each LAO’s and AO’s policies/SOPs and/or IRB requirements, each AO site’s in-country requirements, and each protocol monitoring plan requirements.

Please note that the regulatory binder should contain both the Principal Investigator’s NCI 1572 and NCI Biosketch. The regulatory binder should also contain a note-to-file stating that (1) the NCI Biosketches for all sub-investigators can be found online in the NCI Registration and Credential Repository and that (2) these NCI Biosketches will be provided upon request. The note-to-file should also state that all delegated study tasks are listed on the Delegation of Tasks Log.

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| **Protocol Name:** |
| **Protocol Number:** |
| **Principal Investigator:**  |
| **AO Name and Number:** |

1. **Protocol Information**

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| **Tab Name** | **IND Study Site Binder (SSB)** | **Non-IND Study Site Binder (SSB)** |
| 1.0 Protocol Signature Page (as applicable) or PI Statement of Responsibility |  |  |
| 2.0 [Principal Investigator (PI) Acknowledgement of Package Insert](#IBacknowl) (if applicable) |  |  |
| 3. Principal Investigator (PI) Acknowledgement of Investigator’s Brochure |  | n/a |
| 4.0 Final Approved Case Report Forms (CRF) & CRF Instruction Manuals |  |  |
| 5.0 Study Manuals |  |  |
| 6.0 Monitoring Plan |  |  |
| 7.0 Data and Safety Monitoring Board/Study Monitoring Committee Information  |  |  |
| 8.0 Other, Specify: |  |  |

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| **Protocol Name:** |
| **Protocol Number:** |
| **Principal Investigator:** |
| **AO Name and Number:** |

1. **AO/Site Specific Information**

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| **Tab Name** | **IND Study Site Binder (SSB)** | **Non-IND Study Site Binder (SSB)** |
| **1.0 Personnel** |  |  |
| 1.1 Form FDA 1572 |  | n/a |
| 1.2 CVs or NCI Biosketches,Medical Licenses, GCP Training Certificates, Training Documentation, and Financial Disclosure Form (FDF) |  |  |
| 1.3 Delegation of Tasks Log |  |  |
| 1.4 RCR Registration Verification |  |  |
| **2.0 IRB and Other Approvals** |  |  |
| 2.1 Federal Wide Assurance(s) (FWA) / IRB Registration |  |  |
| 2.2 IRB/EC Member List(s) |  |  |
| 2.3 IRB Submissions |  |  |
| 2.4 IRB/EC Approval(s)/Correspondence |  |  |
| 2.5 IRB/EC Approved Informed Consent Form(s) |  |  |
| 2.6 IRB/ IEC-Approved Participant-Facing Recruitment Materials and Questionnaires |  |  |
| 2.7 IRB/IEC Reviews |  |  |
| **3.0 Laboratory** |  |  |
| 3.1 Laboratory Certification(s) |  |  |
| 3.2 Laboratory Reference Range Values |  |  |
| 3.3 Laboratory Procedures Manual |  |  |
| 3.4 IATA Training (if applicable) |  |  |
| **4.0 Investigational Study Agent** |  |  |
| 4.1 Investigational Agent Accountability |  |  |
| 4.2 Investigational Agent Shipping Receipts/Packing Slips |  |  or n/a |
| 4.3 Sample Label(s) Attached to Investigational Agent |  |  or n/a |
| 4.4 Certificate of Analysis |  |  |
| 4.5 Investigational Agent Storage Temperature Logs |  |  or n/a |
| 4.6 Randomization Code (for Studies That do not Randomize Electronically) |  |  |
| 4.7 Decoding Procedures for Blinded Trials |  |  |
| 4.8 Other Investigational Study Agent Documents |  |  |
| **5.0 Correspondence** |  |  |
| 5.1 General Correspondence Between LAO and AO |  |  |
| 5.2 Internal Correspondence |  |  |
| 5.3 FDA Correspondence |  | n/a |
| 5.4 Communication Logs |  |  |
| **6.0 Resources** |  |  |
| 6.1 Study Specific Procedures |  |  |
| 6.2 Training Tools |  |  |
| 6.3 Study Presentations and Attendance/training Logs |  |  |

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| **Tab Name** | **IND Study Site Binder (SSB)** | **Non-IND Study Site Binder (SSB)** |
| **7.0 Site Visits** |  |  |
| 7.1 Site Visit Log |  |  |
| 7.2 Study Initiation Visit Reports, F/U & Confirmation Letters |  |  |
| 7.3 Interim Monitoring Visit Reports, F/U & Confirmation Letters |  |  |
| 7.4 Closeout Visit, F/U & Confirmation Letters |  |  |
| 7.5 Site Activation & Termination Letters |  |  |
| **8.0 Study Reports** |  |  |
| 8.1 Annual/Interim Analysis/Reports |  |  |
| 8.2 SAEs and Safety Report (Regulatory Agencies/IRBs) |  |  |
| 8.3 Final Clinical/IRB Reports/Publications & Abstracts |  |  |
| **9.0 Protocol Deviations** |  |  |
| 9.1 Protocol Deviations (Minor) |  |  |
| 9.2 Serious Protocol Deviations (Major) |  |  |
| **10.0** **Participant Files** |  |  |
| 10.1 Screening/Enrollment Logs (Enrollment log should include participant identification, and should not leave study site) |  |  |
| 10.2 Miscellaneous Records Retention |  |  |
| **11.0 Miscellaneous** |  |  |
| 11.1 Miscellaneous |  |  |

**References:**

 [ICH/GCP Section 4 Investigator](https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf)

 [ICH/GCP E6 Section 8](https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf)

 For IND studies: FDA 21 CFR Subpart B 50.25 (<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.25>) and Subpart D 312.50 – 312.70

(<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-D?toc=1>)