Dear US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet) Lead Academic Organization (LAO),

This document serves as an example that you as the study sponsor may follow when organizing the regulatory files for your IND and/or Non-IND Master Documentation File (MDF), 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 LAO** based on each protocol’s regulatory requirements, each LAO’s policies/SOPs and/or IRB requirements, each site’s in-country requirements, and each protocol monitoring plan requirements.

Please note that regulatory binders may be either in paper or electronic format. LAOs or their regulatory entities are responsible for FDA IND serial submissions, and for keeping all serial IND submissions in a separate binder/storage location than those outlined in this guidance file. In the case of serial IND submissions, all FDA1572s will be kept in the IND files and do not need to be printed separately (if they are not kept in electronic format).

Additionally, please note that each LAO is responsible for collecting and maintaining regulatory documents from each accruing Affiliate Organization (AO). These documents are in addition to those regulatory documents each LAO is required to maintain as the sponsor for IND and/or Non-IND studies. Each LAO should refer to the title 21 CFR part 312, ICH/GCP guidelines, NIH/NCI guidelines, and the ULACNet Program Guidelines to determine which documents will be necessary to collect and maintain for each study protocol enrolling participants in the ULACNet program (project portfolio).

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

1. **Protocol Information**

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| **Tab Name** | **IND Master**  **Documentation File (MDF)** | **Non-IND Master Documentation File (MDF)** |
| 1.0 Protocol Signature Page or PI Statement of Responsibility (as applicable) |  |  |
| 2.0 Package Insert (if applicable) | or n/a |  |
| 3.0 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 Case Report Forms |  |  |
| 8.0 Laboratory Manual |  |  |
| 9.0 Site Addresses |  |  |
| 10.0 Data and Safety Monitoring Board/Study Monitoring Committee Information |  |  |
| 11.0. Other, Specify: |  |  |

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

1. **LAO Site Information**

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| **Tab Name** | **IND Master Documentation File**  **(MDF)** | **Non-IND Master Documentation File (MDF)** |
| **1.0 Site Personnel** |  |  |
| 1.1 Form FDA 1572 |  | n/a |
| 1.2 CVs or NCI Biosketches,  Medical Licenses, GCP Training Certificates, Study Specific Training Documentation, and Financial Disclosure Forms (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/EC Approval(s)/  Correspondence |  |  |
| 2.4 IRB/EC Approved Informed Consent Form(s) |  |  |
| 2.5 IRB/IEC Approved Participant-Facing Recruitment Materials and Questionnaires |  |  |
| 2.6 Other Approvals |  |  |
| **3.0 Laboratory** |  |  |
| 3.1 Laboratory Certification(s) |  |  |
| 3.2 Laboratory Reference Range Values |  |  |
| 3.3 Laboratory Procedures Manual |  |  |

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| **Tab Name** | **IND Master**  **Documentation File (MDF)** | **Non-IND Master Documentation File (MDF)** |
| **4.0 Investigational Study Agent** |  |  |
| 4.1 Investigational Agent Shipping Records/Packing Slips |  | n/a |
| 4.2 Sample Label(s) Attached to Investigational Agent |  | n/a |
| 4.3 Certificate of Analysis |  | n/a |
| 4.4 Investigational Agent Handling Instructions |  | n/a |
| 4.5 Randomization Code (for Studies That do not Randomize Electronically) |  |  |
| 4.6 Decoding Procedures for Blinded Trials |  |  |
| 4.7 Other Investigational Agent Documents |  |  |
| **5.0 Correspondence** |  |  |
| 5.1 General Correspondence Between LAO and AO, or between LAO and DCP |  |  |
| 5.2 Internal Correspondence |  |  |
| 5.3 FDA Correspondence |  | n/a |
| **6.0 Resources** |  |  |
| 6.1 Training Tools |  |  |
| 6.2 Study-related Presentations and Attendance/training Logs |  |  |

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| **Tab Name** | **IND Master**  **Documentation File (MDF)** | **Non-IND Master Documentation File (MDF)** |
| **7.0 Site Visits** |  |  |
| 7.1 Study Initiation Visit Reports, F/U & Confirmation Letters |  |  |
| 7.2 Interim Monitoring Visit Reports, F/U & Confirmation Letters |  |  |
| 7.3 Closeout Visit Report, F/U & Confirmation Letters |  |  |
| 7.4 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 Miscellaneous** |  |  |
| 10.1 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>)