## APPENDIX F. INITIATION VISIT REPORT FORMS

### DCP PROJECT
### CLINICAL SITE INITIATION VISIT REPORT

## I. SITE INFORMATION

**Instructions:** Please provide the requested information for each of the items listed below. Provide comments whenever necessary or helpful.

Name of Clinical Site:

Protocol Name:

Document Number:

Date(s) of Visit:

Conducted by:

DCP Representative(s) Present:

Clinical Site Personnel Present at the Visit:

| NAME | TITLE | MET WITH CRA MONITOR (Y/N) | PRESENT AT DEBRIEFING (Y/N) |
|---|---|---|---|
| | Principal Investigator | | |
| | Study Coordinator | | |
| | Pharmacist | | |
| | Other | | |

**Additional Comments:**

**CLINICAL SITE**
**INITIATION VISIT CHECKLIST**

| ITEMS VERIFIED and/or DISCUSSED | Y | N | NA | COMMENTS |
|---|---|---|---|---|
| **Background and Purpose of Study** | | | | |
| Study Objectives and Design | | | | |
| **Study Procedures** | | | | |
| Clinical Evaluations | | | | |
| Laboratory Evaluations | | | | |
| Schedule of Evaluations | | | | |
| Specimen Collection, Processing, Storage, and Shipping | | | | |
| Missed Evaluations | | | | |
| Protocol Deviations/Violations | | | | |
| Ordering of Supplies | | | | |
| **Protocol Initiation and Enrollment** | | | | |
| Informed Consent Process | | | | |
| Timing of Pre-Entry Period | | | | |
| Exemptions | | | | |
| Randomization or Enrollment | | | | |
| **Adverse Experience Reporting** | | | | |
| AER Guidelines | | | | |
| Procedures and Forms | | | | |
| Toxicity Management | | | | |
| Receipt, Review, and File Investigator's Brochures | | | | |
| Receipt, Review, and File Package Inserts | | | | |
| Receipt, Review, and File Safety Reports | | | | |
| **Endpoints and Treatment Discontinuation** | | | | |
| Required Evaluations | | | | |
| **Data Collection** | | | | |
| Procedures | | | | |
| CRF Completion Guidelines | | | | |
| Common Errors | | | | |
| Corrections | | | | |
| Form Update Procedures | | | | |
| Missed Visits | | | | |
| Disposition of Forms | | | | |

**CLINICAL SITE**
**INITIATION VISIT CHECKLIST (continued)**

| ITEMS VERIFIED and/or DISCUSSED | Y | N | NA | COMMENTS |
|---|---|---|---|---|
| **Source Documentation** | | | | |
| What Is Acceptable | | | | |
| Shadow Files | | | | |
| Case Report Forms as Source Documents | | | | |
| Document Retention | | | | |
| **Database Management** | | | | |
| System to be Used | | | | |
| Quality Assurance Procedures | | | | |
| Data Queries | | | | |
| Staff to Key CRFs and Other Data | | | | |
| **Policy and Procedure Manuals** | | | | |
| Westat Site Monitoring Manual | | | | |
| Other (list under comments) | | | | |
| **Regulatory Documentation** | | | | |
| Protocol Signature Page | | | | |
| IRB/IEC Documentation | | | | |
| IRB/IEC - Approval Letter | | | | |
| IRB/IEC-Approved Informed Consent Form | | | | |
| IRB/IEC-Approved Advertisements | | | | |
| IRB/IEC-Approved Participant Information Sheets | | | | |
| Annual Renewal | | | | |
| Amendments | | | | |
| IRB/IEC Roster | | | | |
| Assurance Number | | | | |
| Form 1572 | | | | |
| Laboratory Certification | | | | |
| Laboratory Normal Ranges | | | | |
| DHHS and FDA Regulations/GCP Guidelines | | | | |
| OHRP Guidelines for Monitoring | | | | |
| Documentation of IRB/IEC submission of Investigator's Brochures | | | | |
| Documentation of IRB/IEC submission of Package Inserts | | | | |

**CLINICAL SITE**
**INITIATION VISIT CHECKLIST (continued)**

| ITEMS VERIFIED and/or DISCUSSED | Y | N | NA | COMMENTS |
|---|---|---|---|---|
| Documentation of IRB/IEC submission of Safety Reports | | | | |
| Letter of Understanding or Confidentiality Agreement | | | | |
| Submission of Data Safety and Monitoring Plans | | | | |
| Documentation of Human Participants Protection Training | | | | |
| **DCP Reporting Requirements** | | | | |
| Amendments | | | | |
| Adverse Events Reporting Using NCI CTC | | | | |
| Case Report Forms | | | | |
| Progress Reports | | | | |
| Final Reports | | | | |
| Biomarker Methods Report | | | | |
| **Record Keeping Requirements** | | | | |
| Participant Screening Log | | | | |
| Participant Identification Logbook | | | | |
| Master Signature Log | | | | |
| Site Visit Log | | | | |
| Original Signed Informed Consent Forms | | | | |
| Source Documents/Confidentiality | | | | |
| Study-related Correspondence | | | | |
| Telephone Log | | | | |
| **Laboratory Procedures** | | | | |
| Specimen Storage and Disposition | | | | |
| Shipping Procedures | | | | |
| Specimen Shipping Log | | | | |
| **Pharmacy** | | | | |
| Dissemination of Information to the Pharmacist | | | | |
| Drug Storage & Accountability | | | | |
| Pharmacy Guidelines | | | | |
| Current Protocol Versions | | | | |
| Documentation of Informed Consents | | | | |
| Investigator's Brochures | | | | |

**CLINICAL SITE**
**INITIATION VISIT CHECKLIST (continued)**

| ITEMS VERIFIED and/or DISCUSSED | Y | N | NA | COMMENTS |
|---|---|---|---|---|
| Safety Reports | | | | |
| Communication | | | | |
| Quality Assurance Plan | | | | |
| **Quality Assurance (QA) Procedures** | | | | |
| Review QA Plan | | | | |
| Maintain QA Log | | | | |
| **Communication** | | | | |
| With Westat Personnel | | | | |
| With DCP Staff | | | | |
| With CCSA Staff | | | | |
| With Participating Sites | | | | |
| **Study Management** | | | | |
| Copy of Contract | | | | |
| Budget Management and Invoicing | | | | |
| **Site Monitoring** | | | | |
| Purpose | | | | |
| Frequency | | | | |
| Reports | | | | |
| Site Monitoring at Participating Sites (by Lead Site) | | | | |

**ACTION ITEMS IDENTIFIED:**

**ADDITIONAL COMMENTS/GENERAL IMPRESSIONS OF SITE PERFORMANCE:**

Prepared by: Date:

Signature