Regulatory Documentation and Submissions for C2012 Clinical Trials

DCP SOP #1

Phone: 650.691.4400 | Fax: 650.691.4410

Email: regulatory.ccsainc.com
COMPLIANCE & STANDARDIZATION

Rationale for Revision of DCP SOP #1:

• Updated regulatory policies for Good Clinical Practice (GCP)
  NIH Policy on GCP
  ICH E6(R2) GCP
• Minimize complexity through standardization

Most Impacted Essential Regulatory Documents:

• FDA FORM 1572
• Delegation of Task (DOT) Form
• GCP Training Certification
• Financial Disclosure Form
REGULATORY GUIDANCE FOR INDUSTRY

Guidance for Clinical Investigators, Industry, and FDA Staff:

- Statement of Investigator (Form FDA 1572), May 2010
- Financial Disclosure by Clinical Investigators, February 2013
- Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009

NIH Good Clinical Practice:

- Effective January 1, 2017
- Partial Adoption on March 15, 2017
- Full Adoption January 1, 2018

E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1):

- Full Adoption March 1, 2018
- To be applied with ICH guidances relevant to the conduct of clinical trials

  Clinical Safety Data Management: E2A
  Clinical Study Reporting: E3
  Geriatric Populations: E7
  General Considerations for Clinical Trials: E8
  Statistical Principles: E9
  Pediatric Populations: E11
NIH POLICY ON GCP

Scope:

NIH-funded clinical investigators and trial staff responsible for the design, conduct, oversight, or management of clinical trials

Definition:

Investigator: Individual responsible for the design and conduct of the clinical trial at a trial site or, if a team of individuals at a trial site are involved, the investigator leading the team

Clinical Trial Staff: Individuals responsible for study coordination, data collection, and data management

Study Coordination, Data Collection, and Data Management:

Participant recruitment and enrollment
Obtaining informed consent
Data collection and documentation
Regulatory compliance and reporting
ICH E6(R2) GCP

**Scope:** Greater human research subject protection through enhanced quality management systems that offer the following benefits:

- **Sponsor:** Increases oversight and lowers cost
- **Investigator:** Decreases paperwork and facilitates timely communication between the sponsor and regulatory agency
- **Subcontractor/CRO:** Eliminates information redundancies, while enhancing the quality of documents
- **All:** Reduces time taken to file regulatory documents; thereby accelerating conduct of the trial from inception to closure
ICH E6(R2) GCP, continued

**Scope:** CLOs and POs have implemented the following practices to align with recommendation in the ICH’s Integrated Addendum:

- GCP-certified study personnel
- DOT Forms define roles and duties that are considered by the sponsor to make direct and significant contributions to the conduct of the trial
- Study staff members who are considered to make direct and significant contributions to the conduct of the trial are added to FDA FORM 1572
- Documented institutional guidelines that deviate from categorization of study staff/roles are acceptable
- The use of validated digital signatures is a cost effective and expedient alternative to wet-ink documents
### Before Clinical Phase

<table>
<thead>
<tr>
<th>TITLE OF DOCUMENT</th>
<th>LOCATION OF DOCUMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.2.3 INFORMATION GIVEN TO TRIAL SUBJECT</strong></td>
<td>INVESTIGATOR/INSTITUTION</td>
</tr>
<tr>
<td>• Informed consent form (ICF), including translations</td>
<td>x</td>
</tr>
<tr>
<td>• Any other written information</td>
<td></td>
</tr>
<tr>
<td>• Advertisement for subject recruitment</td>
<td></td>
</tr>
<tr>
<td><strong>8.2.7 DATED, DOCUMENTED APPROVAL/FAVORABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB)/INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:</strong></td>
<td></td>
</tr>
<tr>
<td>• Protocol and any amendments</td>
<td>x</td>
</tr>
<tr>
<td>• Case Report Form (CRF)(s)</td>
<td></td>
</tr>
<tr>
<td>• ICF(s), advertisements, and any other written information to be provided to the subject(s)</td>
<td></td>
</tr>
<tr>
<td>• Subject compensation</td>
<td></td>
</tr>
<tr>
<td>• Any other documents given approval/favorable opinion</td>
<td></td>
</tr>
<tr>
<td><strong>8.2.8 IRB/IEC COMPOSITION</strong></td>
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</tr>
<tr>
<td>• IRB membership list</td>
<td></td>
</tr>
<tr>
<td>• OHRC/FWA Assurance</td>
<td></td>
</tr>
<tr>
<td><strong>8.2.9 REGULATORY AUTHORITY(IES) AUTHORIZATION/APPROVAL/NOTIFICATION OF PROTOCOL</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>8.2.10 CURRICULUM VITAE (CV) AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUBINVESTIGATOR(S)</strong></td>
<td>x</td>
</tr>
<tr>
<td>• Medical licenses (ML)</td>
<td></td>
</tr>
<tr>
<td>• GCP Training</td>
<td></td>
</tr>
<tr>
<td><strong>8.2.11 NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>8.2.12 MEDICAL/LABORATORY/TECHNICAL PROCEDURES/TESTS</strong></td>
<td>x</td>
</tr>
<tr>
<td>• Certification</td>
<td></td>
</tr>
<tr>
<td>• Accreditation</td>
<td></td>
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<tr>
<td>• Established quality control and/or external quality assessment</td>
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<tr>
<td>• Other validation</td>
<td></td>
</tr>
</tbody>
</table>
### During Clinical Conduct of the Trial

<table>
<thead>
<tr>
<th>TITLE OF DOCUMENT</th>
<th>LOCATION OF DOCUMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.3.1</strong> INVESTIGATOR’S BROCHURE UPDATES</td>
<td>INVESTIGATOR/INSTITUTION: X; SPONSOR/CRO: X</td>
</tr>
<tr>
<td><strong>8.3.2</strong> ANY REVISIONS TO:</td>
<td>INVESTIGATOR/INSTITUTION: X; SPONSOR/CRO: X</td>
</tr>
<tr>
<td>• Protocol/amendments and CRFs</td>
<td></td>
</tr>
<tr>
<td>• ICF(s), advertisements, and any other written information to be provided to the subject(s)</td>
<td></td>
</tr>
<tr>
<td><strong>8.3.3</strong> DATED, DOCUMENTED APPROVAL/FAVORABLE OPPINION OF IRB/IEC OF THE FOLLOWING:</td>
<td>INVESTIGATOR/INSTITUTION: X; SPONSOR/CRO: X</td>
</tr>
<tr>
<td>• Protocol amendments</td>
<td></td>
</tr>
<tr>
<td>• ICF(s), advertisements, and any other written information to be provided to the subject(s)</td>
<td></td>
</tr>
<tr>
<td>• Any other documents given approval/favorable opinion</td>
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<tr>
<td>• Continuing review of trial</td>
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</tr>
<tr>
<td><strong>8.3.4</strong> REGULATORY AUTHORITY (IES) AUTHORIZATION/APPROVAL/NOTIFICATION OF PROTOCOL</td>
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</tr>
<tr>
<td>• Protocol amendments and other documents</td>
<td></td>
</tr>
<tr>
<td><strong>8.3.5</strong> CV AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS FOR NEW INVESTIGATOR(S) AND SUBINVESTIGATOR(S)</td>
<td>INVESTIGATOR/INSTITUTION: X; SPONSOR/CRO: X</td>
</tr>
<tr>
<td>• MLs</td>
<td></td>
</tr>
<tr>
<td>• GCP Training</td>
<td></td>
</tr>
<tr>
<td><strong>8.3.6</strong> UPDATES OF NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL</td>
<td>INVESTIGATOR/INSTITUTION: X; SPONSOR/CRO: X</td>
</tr>
<tr>
<td><strong>8.3.7</strong> UPDATES OF MEDICAL/LABORATORY/TECHNICAL PROCEDURES/TESTS</td>
<td>INVESTIGATOR/INSTITUTION: X; SPONSOR/CRO: X</td>
</tr>
<tr>
<td>• Certification</td>
<td></td>
</tr>
<tr>
<td>• Accreditation</td>
<td></td>
</tr>
<tr>
<td>• Established quality control and/or external quality assessment</td>
<td></td>
</tr>
<tr>
<td>• Other validation</td>
<td></td>
</tr>
</tbody>
</table>
Protocol-specific Auto-filled Content:

Global and Local FDA FORM 1572 will include the following:

• Protocol number and title
• Central laboratory name and address(s)
• Central IRB (CIRB) name and address

Financial Disclosure Form will include the following:

• Protocol number and title

Delegation of Task Form will include the following:

• Protocol number and title
Prior to FDA Submission of Protocol

Global FDA FORM 1572, Consortium Principal Investigator’s CV

DCP Regulatory Contractor

FDA Activation of Protocol

CIRB Initial Approval of Protocol

DCP Regulatory Contractor

Protocol-specific Regulatory Template Distribution to CLOs
SUMMARY OF CHANGES BY REGULATORY DOCUMENT TYPE

- Global FDA FORM 1572 (By Section)
- Local FDA FORM 1572 (By Section)
- DOT Form
- IB Acknowledgement or Packet Insert
- Curriculum Vitae
- Medical License
- Financial Disclosure Form
- GCP Training Certificate
- CLIA
- CAP
- Lab Values

- OHRP Assurance
- CIRB/IRB Approval
- IRB Continuing Approval
- IRB Closure
- IRB Modification
- Local IRB Deferral/Approval
- Informed Consent
- Patient Materials

* Highlighted Document Types Reflect DCP SOP #1 Changes
GLOBAL FORM FDA 1572

Time Point and Criteria for Collection:

- Initial FDA protocol submission
- Participating Organization (PO) change
- Completed drug shipment authorization (DSA) for all POs *if content revised from initial FDA submission*
- CLO Principal Investigator (PI) or PO PI change

Form Content:

Section 1: CLO PI only

Section 2: Continuation page with content and correct pagination

Section 3: Complete list of clinical facilities where patients are treated

Section 4: Complete list of clinical laboratories
  - Central lab names and addresses auto-filled by DCP
  - Regulatory Contractor
  - Local labs to be added by PO
GLOBAL FORM FDA 1572, continued

Form Content:

Section 5: CIRB name and address auto-filled by DCP Regulatory Contractor
Local IRB of Record to be added by PO (if applicable)

Section 6: PO PIs only (include statisticians only if not under any PO’s
Local FORM FDA 1572)

Section 7: Protocol number and title auto-filled by DCP Regulatory Contractor

Section 8: Handwritten signature accompanied by handwritten date only OR
digital signature submitted without PDF error
LOCAL FORM FDA 1572

Time Point and Criteria for Collection:

- Prior to DSA
- Within 30 days after any revision to content

Form Content:

Section 1: PO PI only
Section 2: Continuation page with content and correct pagination
Section 3: Complete list of PO’s clinical facilities where patients are treated
   Drug shipment address included and labeled
   *(see below example)*
Section 4: Complete list of clinical laboratories
   Central lab names and address auto-filled by DCP Regulatory Contractor
   Local labs to be added by PO
LOCAL FORM FDA 1572, continued

Form Content:

Section 5: CIRB name and address auto-filled by DCP Regulatory Contractor
Local IRB of Record to be added by PO *(if applicable)*

Section 6: PO SIs indicated by duties performed on DOT Form

Section 7: Protocol number and title auto-filled by DCP Regulatory Contractor

Section 8: Handwritten signature accompanied by handwritten date only OR digital signature submitted without PDF error
**LOCAL FORM FDA 1572, continued**

### Drug Shipment Label

<table>
<thead>
<tr>
<th>Name of Medical School, Hospital, or Other Research Facility</th>
<th>Address 1</th>
<th>Address 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC San Diego Moores Cancer Center - Investigational Drug Services</td>
<td>3855 Health Sciences Drive, Room 1036</td>
<td>92037-0845</td>
</tr>
<tr>
<td>City</td>
<td>La Jolla</td>
<td>CA</td>
</tr>
</tbody>
</table>

**Address 5**

<table>
<thead>
<tr>
<th>Name of Medical School, Hospital, or Other Research Facility</th>
<th>Address 1</th>
<th>Address 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC San Diego - Investigational Drug Services</td>
<td>92037-0845</td>
<td>92037-0845</td>
</tr>
<tr>
<td>City</td>
<td>La Jolla</td>
<td>CA</td>
</tr>
</tbody>
</table>

**Name of Medical School, Hospital, or Other Research Facility**

<table>
<thead>
<tr>
<th>Address 1</th>
<th>Address 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC San Diego Medical Center - Hillcrest</td>
<td>206 West Arbor Drive</td>
</tr>
<tr>
<td>City</td>
<td>San Diego</td>
</tr>
</tbody>
</table>

**Add Second Continuation Page for Item 5**

**Return to Form**
DOT FORM

Time Point for Collection:
- Prior to DSA
- Within 30 days after any revision to content
- Completion of study

Form Content:
- Separate DOT Form for all study staff members except PI
- DOT Form does not need to be original

Section I: Study title and DCP protocol number auto-filled by DCP
Regulatory Contractor
Local protocol number to be added by PO

A Separate Delegation of Tasks Log must be completed by each Study Staff member.
Form Content:

Section II: To be completed by PO PI and study staff member
PO PI’s acknowledgment date of staff may not precede the
staff member’s signature date
Form Content:

Section III: To be signed by PO PI at the completion of study

The Site Investigator will sign above at the beginning of study and sign below when study is complete. If the staff member's position or tasks change during the study lifecycle, use additional lines to record new position tasks. (Reference: FDA Guidance for Industry Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects, 2009)

<table>
<thead>
<tr>
<th>Study Information III</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Investigator Signature at conclusion of the study:</td>
<td></td>
</tr>
</tbody>
</table>
DOT FORM, continued

Criteria for Collection:

- Tasks assigned appropriate to training and qualifications
- Below-numbered tasks make a direct and significant contribution to the study data
- Staff members performing below-numbered tasks (physicians, nurses, coordinators, pharmacists) are considered SIs and should be added to Local FORM FDA 1572 and complete a Financial Disclosure Form.*

1 - Obtain and administer informed consent
2 - Recruit patients
3 - Determine patient eligibility
4 - Recruit patients
6 - Complete source documents
8 - Perform physical exams
10 - Obtain medical history
11 - Dispense study medication
12 - Report serious adverse events
13 - Instruct patients on study procedures
14 - Complete case report forms
16 - Adverse event assessment/attribution
17 - Data analysis (statistician)
20 - Adverse event assessment/attribution
21 - Site Investigator out of office coverage

*PO’s SOP or NTF requested if local policy states otherwise.
CURRICULUM VITAE

Time Point for Collection:
• Prior to DSA
• As staff members are added to the study after DSA

Criteria for Collection:
• CV or biosketch is required for CLO PIs, PO PIs, SIs, and all other staff members listed on DOT Form

Form Content:
• Within two years of DSA or initial date of involvement if added after DSA
• Displays study staff member’s current affiliation and dates of involvement with the PO
• Staff member’s dated signatures are not required
• CV or biosketch dates can be ascertained from the content
FINANCIAL DISCLOSURE FORM

Time Point for Collection:

- Prior to DSA
- As staff members are added to the study after DSA
- Within 30 days after any revision to content

Criteria for Collection:

- Financial Disclosure forms must be signed and dated by all study staff on Global and/or Local FORM FDA 1572

Form Content:

- Protocol number and title auto-filled by DCP Regulatory Contractor
- Attached list of disclosures should be typed
- Handwritten signature accompanied by handwritten date OR digital signature submitted without PDF error
GCP TRAINING CERTIFICATION

Time Point for Collection:
- Prior to DSA
- As staff members are added to the study after DSA
- Upon expiration (*if applicable*)

Criteria for Collection:
- GCP training is required for all personnel listed on the Global and Local FORMs
- FDA 1572 and the DOT Form

Form Content:
- GCP training certification from NIH or the staff members’ own institution is acceptable
- Expiration of GCP training is based on training provider/institution
- Expiration dates should be listed on certificates or should be clarified through an institutional NTF if they do not expire
IRBs OF RECORD

Time Point for Collection:

- Prior to DSA
- Amendment of protocol, informed consent, and/or patient materials
- Continuing review
- Study termination and/or closure

IRBs of Record:

- CIRB
- Independent Ethics Committee (IEC)
- Local IRB, Veterans Affairs (VA) IRB

Criteria for Collection:

- IRB approval required from each IRB of Record listed on the Global and Local FDA FORM 1572
- POs outside US territories require IEC approval in addition to CIRB approval
- VA Healthcare Networks require VA IRB approval
CIRB APPROVAL

Time Point for Collection:

- Prior to DSA
- Amendment of protocol, informed consent, and/or patient materials
- Continuing review
- Study termination and/or closure

CIRB as IRB of Record:

- CIRB approval of protocol, informed consent, and/or patient materials
- Local IRB deferral letter confirming reliance on the CIRB
- Local IRB approval (if applicable)
- Approval of Study Specific Worksheet
LOCAL IRB APPROVAL

Time Point for Collection:

- Prior to DSA
- Amendment of protocol, informed consent, and/or patient materials
- Continuing review
- Study termination and/or closure

Only Local IRB as IRB of Record:

- Local IRB approval of protocol, informed consent, and/or patient materials
IEC APPROVAL

Time Point for Collection:

- Prior to DSA
- Amendment of protocol, informed consent, and/or patient materials
- Continuing review
- Study termination and/or closure

Criteria for Collection:

- POs outside US territories may require multiple IEC approvals (national and institutional)
- CIRB and IEC approval of protocol versions may differ at the time of DSA if Final Approval of the study has been granted by DCP

IEC as IRB of Record:

- IEC approval of protocol, informed consent, and/or patient materials
- CIRB approval of protocol, informed consent, patient materials, and translations
- Approval of Study Specific Worksheet
INFORMED CONSENT & PATIENT MATERIALS

Time Point for Collection:

- Prior to DSA
- Amendment of informed consent and patient materials
- Continuing review *(if applicable)*

CIRB as IRB of Record:

- CIRB-approved boilerplate informed consent (version/date listed on CIRB approval)
- Local version of the informed consent
- Local version and date may differ from CIRB-approved boilerplate, as each institution has unique guidelines for versioning *(see Institutional IRB Practices)*

Only Local IRB as IRB of Record:

- Local IRB version of the informed consent (version/date listed on Local IRB approval)
INFORMED CONSENT & PATIENT MATERIALS, continued

Time Point for Collection:

- Prior to DSA
- Amendment of informed consent and/or patient materials
- Continuing review *(if applicable)*

IEC as IRB of Record:

- CIRB-approved boilerplate informed consent (version/date listed on CIRB approval)
- Local and/or translated version of the informed consent (version/date listed on IEC approval)
- Local version and date may differ from CIRB-approved boilerplate, as each institution has unique guidelines for versioning
## INSTITUTIONAL IRB PRACTICES

<table>
<thead>
<tr>
<th>Institution Name</th>
<th>NCI IRB Approval</th>
<th>Local IRB Approval/Deferal Letter</th>
<th>Local IRB Review of Amendments</th>
<th>Locally Stamped ICF</th>
<th>Local ICF Approval Date</th>
<th>Local ICF Expiration Date</th>
<th>Local ICF Protocol Date/Version</th>
<th>Local HIPAA Form</th>
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</thead>
<tbody>
<tr>
<td>Cedar Sinai Medical Center</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Cleveland Clinic Cancer Center</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Columbia University Medical Center</td>
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<tr>
<td>Dana Farber Cancer Institute/Brigham Women</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Duke Cancer Center</td>
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<td>E.O. Dospedal Gallery</td>
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<td>European Institute of Oncology</td>
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<td>Georgetown University Medical Center</td>
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<td>Yes</td>
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<td>Huntsman Cancer Institute (University of Utah)</td>
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<td>Johns Hopkins Oncology Center</td>
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<td>Yes</td>
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<td>Kaiser Permanente</td>
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<td>Kansas City VA</td>
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<td>Massachusetts General Hospital</td>
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<td>Yes</td>
<td>Yes</td>
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<tr>
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QUESTIONS?

Thank You

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Email: mbagoly@ccsainc.com