Clinical Research Shared Service Standard Operating Procedure

SOP 202-DMG Data Management of Clinical Research Trials

Approval signature: Michael Bookman, M.D., Director of CRSS

Approval date: 22DEC2011

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Purpose:
This standard operating procedure (SOP) describes the processes followed at the University of Arizona Cancer Center (UACC) for the collection of clinical research data, transcription of the data to case report forms (CRFs) and the management of the data, including procedures for:
- quality control;
- confidentiality;
- data query resolution;
- record retention and archiving.

This SOP applies to data management for all clinical studies subject to investigational new drug (IND) regulations for drugs, biologics and investigational device exemptions (IDE) for devices and diagnostics during all investigational phases of development.

References:
- 21 CFR 312.50 General responsibilities of sponsors
- 21 CFR 312.56 Review of ongoing investigations
- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.62 Investigator record keeping and record retention
- 21 CFR 312.64 Investigator reports
- 21 CFR 312.68 Inspection of investigator's records and reports
- 21 CFR 312.70 Disqualification of a clinical investigator
- FDA Information Sheets October 1995, Record keeping in Clinical Investigations
- January 1988 Guidelines for the Monitoring of Clinical Investigations
- May 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline
- http://www.irb.arizona.edu/hipaa.html
- All SOPs are applicable to this SOP.

Author(s):
Revised by SOPRC.
Target Audience or Responsibilities:
This SOP applies to those members of the clinical research team involved in data collection, transcription to CRFs, and the management of the data.
- Investigators (PI, Local or Co-PI, Sub-Investigators)
- Clinical Research Shared Services personnel
- Investigational Pharmacist
- IRB (Institutional Review Board)/IBC (Institutional Biosafety Committee)
- Support Staff

Tools:
- List of Logs Kept for Each Study
- Source Documentation Requirements
- Data Clarification Form
- CRIS (Cancer Research Information System)
- Adverse event flow sheets
- Concomitant medications flow sheet
- UACC Research patient questionnaire
- Patient Screening Form

Definition of Terms:
- Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.
- Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor’s proprietary information or of a subject’s identity.
- Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, optical records; and scans, X-rays, and electrocardiograms) that describes or records the methods, conduct, and/or results of a trial, the factors affecting a trial and the actions taken.
- Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.
- Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded) and reported in compliance with (GCP) and the applicable regulatory requirement(s).
- Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).
- Source Documents: Original documents, data, and records including, but not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subject’s diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, X-rays,
SOP 202-DMG  Data Management of Clinical Research Trials

subject files, and records kept at the pharmacy, at the laboratories and at medical-
technical departments involved in the clinical trial.

Safety Issues:
The availability of SOPs in a standard format enhances the safe delivery of clinical research
practice and ensures compliance with appropriate guidelines.

Process Steps:
Collection of clinical research data:
1. Clinical Trials Office:
   • Will obtain all study-related regulatory documentation.
   • Ensure that copies of the most recent IRB-approved consent form are available
     and provided to the Data Manager for incorporation into the study packet.
2. Data Manager and/or Research Nurse Coordinator:
   • Based upon the protocol and case report forms, develop study-specific
     organizational aids, source documentation, checklists and logs (Example:
     Attachments 1 through 7).
   • Obtain medical records/source documentation.

Transcription of the data to case report forms (CRFs):
1. Data Manager and/or Research Nurse Coordinator:
   • Record all required documentation in CRFs according to sponsor specifications
     from source documents following ALCOA standard (attributable, legible,
     contemporaneous, original, accurate).
   • Correct CRF errors by striking through the error with a single line, dating and
     initialing the correction and entering the correct data (unless otherwise instructed
     by the sponsor’s instructions). Ensure the original entry remains visible. If
     necessary, note the reason for the correction. Follow sponsor-specific instructions
     for remote data CRF corrections. Investigator-initiated studies are entered into
     CRIS, which has an incorporated audit trail.
   • Utilize only the subject initials and study identification number. Ensure there is no
     subject identifying information (name, history number, social security number etc.)
     in the CRF.
   • Obtain Principal Investigator’s signature on required.

Management of the data, including procedures for:
• Quality control
• Confidentiality
• Data query resolution
• Record retention and archiving
1. Clinical Trials Administration Office:
   a. Will manage and maintain all study-related regulatory documentation.
2. Data Manager and/or Research Nurse Coordinator:
   a. Request a copy of the sponsor's case report form completion guide and a copy of the sponsor's SOP for making changes or corrections to case report forms (if CRF corrections are not already addressed in the completion guide).
   b. Interim requests from the sponsor for data transmissions between regularly scheduled monitoring visits will be reviewed on a case-by-case basis by the PI and/or the clinical research team to which the study is assigned.
   c. In the event the sponsor revises the original CRFs, previously transcribed data will not be re-transcribed onto the new forms.
   d. All data as authorized by the subject authorization form for use and disclosure of protected health information (PHI) for research, that may include subject identifiers, that require release from the study site will be de-identified to protect the subject's confidentiality.
   e. Collect any discrepancies noted at the sponsor's monitoring visit on a data clarification form to ensure a trail of clarifications and corrections. If a sponsor-specific form is not available, ensure that any discrepancies are noted on a generic data clarification form (Attachment 3, Data Clarification Form).
   f. Ensure that data clarification forms are kept with the subject-specific CRF. Place DCFs in the front of the CRF unless a specific tab is provided.
   g. At the conclusion of the study, ensure that data are retained according to regulatory and sponsor requirements.
   h. At study conclusion, inform the sponsor on the procedure to archive records and location of archived records.
   i. Inform the sponsor of the study in writing and obtain approval prior to destroying any study-related documents.
<table>
<thead>
<tr>
<th>List of Logs Kept for Each Study</th>
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<tbody>
<tr>
<td>□ Subject screening/enrollment log</td>
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<tr>
<td>□ Subject identification list</td>
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<tr>
<td>□ Site signature log</td>
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<tr>
<td>□ Serious Adverse Event (SAE) log</td>
</tr>
<tr>
<td>□ Record of retained body fluids/tissue samples (if appropriate)</td>
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<tr>
<td>□ Monitoring log</td>
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</table>
For each study, source documentation to support case report form data should include the following:

1. Date of entry into the study, sponsor’s protocol number and subject number.

2. Note that written informed consent was obtained; consent form dated and signed by subject (or subject’s legal representative).

3. Record any current medications and medications discontinued within the last month (or longer, as specified by the protocol).

4. Record subject’s diagnosis and status prior to treatment, including documentation of medical history, particularly that relevant for the disease or condition being treated.

5. Record names, doses and dosing times (if applicable) of all study drugs and/or research procedures or assessments.

6. Document the dates, results, evaluations and procedures required by the study; note any deviations from the protocol and provide an explanation.

7. Record any reported complaints, changes or adverse events that occurred during the treatment period and for a period specified by the sponsor following the last dose of study drug. Record any treatment administered and/or recommended.

8. Record subject’s condition during and/or after treatment.

9. Document final disposition of the subject and subject status at time of study termination.
# Data Clarification Form

**HSC #:** ____________________  
**Study Title:** ____________________  
**Sponsor:** ____________________  
**Investigator:** ____________________  

<table>
<thead>
<tr>
<th>Pt. #</th>
<th>Initials</th>
<th>CRF PAGE</th>
<th>Clarifications</th>
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<th>Initials</th>
<th>Date</th>
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Signature of Monitor completing the form  

Signature of Data Manager or Research Nurse Coordinator completing the form  

Investigator's Signature ____________________  
Date ______/_____/______
### Site Screening Log

<table>
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<tr>
<th>Subject Number</th>
<th>Subject Initials</th>
<th>DateConsented or Refused*</th>
<th>Disease</th>
<th>Date Registered or Randomized</th>
<th>Treatment Level</th>
<th>Off Study Date</th>
<th>Off Study or Non Registration Reason</th>
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**COMMENTS:**

* = Subjects refusing enrollment prior to signing an informed consent form

Final Version 12-13-2011 Rev F
## Site Signature Log

<table>
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<tr>
<th>Name (Please Print)</th>
<th>Full Signature</th>
<th>Designation/Title</th>
<th>Start Date of Staff Participation</th>
<th>End Date of Staff Participation</th>
<th>Abbreviated Signature (Initials)</th>
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**COMMENTS:**

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**Final Version 12-13-2011 Rev F**
### Retained Body Fluids/Tissue Samples

**HSC #:**

**Study Title:**

**Sponsor:**

**Investigator:**

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Subject Initials</th>
<th>Date Consented</th>
<th>Sample Type</th>
<th>Sample Date</th>
<th>Storage Location</th>
<th>Date Sent to Sponsor</th>
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**COMMENTS:**

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Final Version 12-13-2011 Rev F
## Monitoring Log

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<tr>
<th>Arrival Date/Time</th>
<th>Sponsor</th>
<th>Sponsor Representative</th>
<th>Visit Type</th>
<th>RN</th>
<th>DM</th>
<th>Visit Complete</th>
<th>Exit Evaluation Form Completed</th>
<th>Exit Date/Time</th>
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**COMMENTS:**

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Final Version 12-13-2011 Rev F