How to Write and Format an University of Arizona Cancer Center (UACC) Clinical Research Standard Operating Procedure

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

Approval Date: 2/10/2011

Original approval date: 4/22/02

Revision dates: 4/8/03, 2/19/04, 5/10/04, 4/17/06, 10/22/08, 12/12/11

Purpose:
To standardize a format to develop, write and approve University of Arizona Cancer Center (UACC) Clinical Research standard operating procedures (SOP).

References:
- University of Arizona Medical Center (UAMC) SOPs as appropriate;

Author:
Revised by SOPRC.

Target Audience or Responsibilities:
Personnel who write UACC Clinical Research SOPs.

Tools:
- Electronic SOP template
- Paper copy SOP
- SOPRC membership list (See attachment 1)
- SOP Development Checklist (See attachment 2)

Definition of Terms:
Purpose of definitions is to clarify terms used within each SOP.
- Approval signature: Director of Clinical Research Shared Service (CRSS).
- Approval date: The date that the CRSS director approved the latest version of the SOP document.

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• **Author(s):** Title of person, group, or committee writing SOP.
• **Effective date:** Within 30 days of approval date unless otherwise specified.
• **Original approval date (in relation to SOPs):** Original SOP approval signature date as noted by the Clinical Research Shared Service Director. This will remain consistent throughout the SOP history.
• **Process steps:** Sequential steps, activity or tasks needed to carry out the SOP.
• **References:** Sources of information used to aid in writing SOP and/or identify related SOP(s) and other policies and procedures (See Reference list for format to list references).
• **Revision date(s) (in relation to SOPs):** The date(s) that the SOP document was revised.
• **Safety Issues:** Identify any potential harmful effect to staff, patients, or individual(s) involved in carrying out the SOP.
• **SOPRC:** Standard Operating Procedure Review Committee.
• **Standard Operating Procedure (SOP):** Detailed written instructions to achieve uniformity of the performance of a specific function.
• **Target audience:** Personnel affected by and/or responsible for carrying out the SOP.

**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:**
1) Identify the need for the SOP.
2) Check if an SOP already exists.
3) Build a group of key players to develop the SOP. Try not to exceed 5 people. Set a timeline to complete the SOP.
4) Contact the group by e-mail or by phone, if necessary, to convene a meeting.
5) Set up a meeting time and place. Provide members of the group with a copy of SOP 101 ADM.
6) Review SOP 101-ADM (key step).
7) Identify the target audience.
8) Decide on a working title for the SOP.
9) Identify references/resources and gather tools required to write and support the SOP.
10) Define terms using terms from the definition of terms glossary for consistency.
11) Identify any safety issues.
12) Write process steps.
13) Cite references/resources used.
14) Identify authors.
15) Write draft of SOP using SOP 101-ADM template.
16) Convene group meeting to review draft.
17) Make necessary revisions.
18) Submit final draft to SOP Review Committee (SOPRC). Submission must include a SOP Development Checklist (attachment 2) and a list of all references.
19) Submit to SOP Review Committee (SOPRC) Chairperson or designee.
20) In general, approved SOPs should be revised within 3 years from the most recent approval date, even in the absence of an amendment.
Attachment 1

SOPRC Membership List

Michael Bookman (Chair)  Mbookman@azcc.arizona.edu
Toby Aparisi             taparisi@azcc.arizona.edu
Jeanette Cardenas        jcardenas@azcc.arizona.edu
Carrie Ma                cma@azcc.arizona.edu
Elleen Martin            emartin@azcc.arizona.edu
Heather Wright           hwright@azcc.arizona.edu
Attachment 2  SOP Development Checklist

Standard Operating Procedures Review Committee
Pre-committee Review
SOP Development Checklist

SOP Title: ____________________________  SOP # __________

Is this a new SOP draft?  ☐ Yes  ☐ No  ☐ Original submission date: ____________  ☐ Resubmission date: ____________

Is this a revision of a previously submitted SOP?  ☐ Yes  ☐ No

Please complete the checklist below.

<table>
<thead>
<tr>
<th>Original submission</th>
<th>Resubmission</th>
<th>Item</th>
<th>SOPRC ONLY Original submission</th>
<th>SOPRC ONLY Resubmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>1. Has the area supervisor been informed of this SOP?</td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>Area Supervisor Signature:</td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>2. Does this SOP conflict with an existing SOP?</td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>3. Have you obtained input from key individuals affected by the SOP?</td>
<td></td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>4. Have you included a complete list of the resource material/references used to write the SOP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>5. Have you used the SOP format identified in AZCC SOP 101-ADM?</td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>6. Have you used clear and concise language?</td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>7. Have you used active rather than passive verbs?</td>
<td></td>
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<tr>
<td>☐ Yes  ☐ No</td>
<td>☐ Yes  ☐ No</td>
<td>8. Have you identified the essential process steps?</td>
<td></td>
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</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
<th>9. Have you listed the contact person's name, phone number and email address?</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td>Name: ___________________________</td>
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<td>Phone number: __________________</td>
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<td></td>
<td>Email address: ________</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>10. Have you included a copy of this checklist with your draft SOP?</td>
</tr>
</tbody>
</table>

For SOPRC USE

Initial submission: Date received ___________  Final Pre-Committee Review/Approval Date ___________

Resubmission: Date received ___________