Title: Standard Operating Procedures

<table>
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<tr>
<th>SOP #</th>
<th>Revision</th>
<th>Effective Date</th>
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<tr>
<td>HRP-071</td>
<td>#1</td>
<td>09/29/2014</td>
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Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC  Date: 3/21/14

Approved: Richard Larson, MD PhD Vice Chancellor for Research  Date: 9/23/14

1 PURPOSE
1.1 This procedure establishes the process to create and update standard operating procedures (SOPs) and associated checklists, worksheets and user guides.
1.2 The process begins when the HRPP Director or Vice Chancellor for Research determines that a new SOP is required or an existing SOP requires modification.
1.3 The process ends when the new or revised standard operating procedure has been approved, filed and uploaded to the electronic software database.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP.
2.2 Replaced all references to “IRB” with “HRRC.”

3 POLICY
3.1 A comprehensive set of SOPs is required to reflect the current operational procedures for the Human Research Protections Program (HRPP), including the use of all critical resources (for example operational software) and to ensure adherence to regulatory guidelines.

4 RESPONSIBILITIES
4.1 The HRPP Director or designee carries out these procedures.

5 PROCEDURE
5.1 For a new SOP, a number is assigned according to the existing number sequencing convention and nomenclature.
5.2 For each revision to an existing SOP, the original SOP number is retained, and the revision number increases by 1.
5.3 The author will create or update the SOP following the “TEMPLATE SOP (HRP-505)” or equivalent and/or update any associated forms.
5.4 Have the revised or new SOP reviewed by the HRRC executive chair and forward his/her recommendation for approval to the Vice Chancellor for Research for final approval and signature.
5.5 Once approved:
5.5.1 File the approved new or revised document in the Master SOP binder.
5.5.2 Upload the approved new or revised document to the electronic software database.
5.5.3 File the old document, if applicable, in the standard operating procedure history files.
5.5.4 Send an email to affected individuals informing them of the change.
5.5.5 Review the associated handbooks, user guides, worksheets and checklists to ensure that they are consistent with the new or revised SOP. Update items as necessary.

5.6 Maintain a training log for each SOP in the SOP binder.
5.6.1 HRPO new and existing staff training will include review of the SOPs.
5.6.2 SOP review and training will occur and will be documented no less than every two years.
5.6.3 The SOP training curriculum will include a 360 degree discussion and review by the HRPO staff of the effectiveness of the SOPs being reviewed and whether the HRPO and the HRRCs can and are complying with the provisions of those SOPs.

6 MATERIALS
6.1 TEMPLATE SOP (HRP-505) or equivalent

7 REFERENCES
7.1 None