### University of Kentucky
#### Investigational Device Accountability

**Protocol #:**

**Investigator Name:**

**Protocol Title:**

**Device Name/Description/IDE #:**

- [ ] significant risk device
- [ ] non-significant risk device
- [ ] humanitarian use device
- [ ] treatment investigational new device exemption
- [ ] exemption from IDE

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**DEVICE RECEIPT**

<table>
<thead>
<tr>
<th>Date Rec'd</th>
<th>Quantity</th>
<th>Initials of Recipient</th>
<th>Device Component(s)</th>
<th>Serial # or Model #</th>
<th>Batch #</th>
<th>Date Used</th>
<th>Subject ID</th>
<th>Quantity Used</th>
<th>Initials of Person Distributing</th>
<th>Records of shipment to/from supplier/sponsor kept:</th>
</tr>
</thead>
<tbody>
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<td>[ ] Yes  [ ] No  [ ] N/A</td>
</tr>
</tbody>
</table>

**DEVICE USE**

<table>
<thead>
<tr>
<th>Date Used</th>
<th>Subject ID</th>
<th>Quantity Used</th>
<th>Initials of Person Distributing</th>
<th>Ret=Returned</th>
<th>Des=Destroyed</th>
<th>Rep=Repaired</th>
<th>Date</th>
<th>Initials</th>
<th>Quantity</th>
<th>Reason</th>
</tr>
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**DEVICE RETURN / REPAIR / DESTRUCTION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Initials</th>
<th>Quantity</th>
<th>Reason</th>
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**COMMENTS**

- Study log coincides with current inventory:
  - [ ] Yes  [ ] No  [ ] N/A

- Returns and expired device(s) identified and separate from active inventory:
  - [ ] Yes  [ ] No  [ ] N/A

- Other:
  - [ ]

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December 2010
### DEVICE STORAGE

**Description in Protocol:**
1. Storage Site(s) Matches Description in Protocol
   - Yes ☐ No ☐ N/A

**Comments:**
2. Storage area secured with limited access
   - Yes ☐ No ☐ N/A
3. Device(s) properly labeled “For Investigational Use” and stored separately from other devices.
   - Yes ☐ No ☐ N/A
4. If subject self-administration applies, are appropriate directions for use of the device attached/provided?
   - Yes ☐ No ☐ N/A
5. Device(s) requiring special conditions (i.e., room temp. log, protect from light, etc.) are properly maintained.
   - Yes ☐ No ☐ N/A

### MONITORING

**Description in Protocol:**
- Documentation that device safety information reviewed & evaluated per protocol (i.e., DSMP executed)
  - Yes ☐ No ☐ N/A

**Comments:**

### RESEARCH RECORDS:

**IRB Approved estimate of # of subjects to be given the device:** _______

**Number of subjects given the device to-date:** _______

**Comments**

1. A current copy of protocol available and kept in a secure area.
   - Yes ☐ No ☐ N/A
2. A current Investigational Plan is available and kept in a secure area (req. for SR devices only).
   - Yes ☐ No ☐ N/A
   - Yes ☐ No ☐ N/A
4. Names of investigator, coordinator and sponsor are available.
   - Yes ☐ No ☐ N/A
5. Pertinent information on study device available for subject.
   - Yes ☐ No ☐ N/A
6. Consent forms are being obtained on every subject prior to enrolling the subject into the study and are kept in a secure area.
   - Yes ☐ No ☐ N/A
7. Documentation is being completed/signed by authorized personnel.
   - Yes ☐ No ☐ N/A
8. Policy for receipt and control of device is available.
   - Yes ☐ No ☐ N/A
9. Policy for dispensing/use of device is available.
   - Yes ☐ No ☐ N/A
10. Policy for return/disposal/destruction of device (if applicable) is available.
    - Yes ☐ No ☐ N/A

**Other Comments:**

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