# AUDIT WORKSHEET 3

<table>
<thead>
<tr>
<th>Auditor:</th>
<th>Date:</th>
<th>IRB#</th>
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## PROTOCOL COMPLIANCE

1. Inclusion/Exclusion criteria met per IRB approved protocol:
   - Yes □ No □ N/A □
   - Comments: 

2. Screening, study treatment/procedures, performed per IRB approved protocol:
   - Yes □ No □ N/A □
   - Comments: 

3. Study administered by IRB authorized personnel only and at approved sites:
   - Yes □ No □ N/A □
   - (Look for signatures or notes by personnel not on the list, especially in CRFs)
   - Comments: 

4. Only IRB protocol approved concomitant – treatment or medications administered:
   - Yes □ No □ N/A □
   - Comments: 

5. Modifications to the study protocol prior to IRB approval or exemption:
   - Yes □ No □ N/A □
   - Comments: 

6. IRB approved study protocol follow-up procedures performed:
   - Yes □ No □ N/A □
   - Comments: 

7. Drug, Device or test article administration errors:
   - Yes □ No □ N/A □
   - Comments: 

*Updated F1419 LR*