This worksheet is intended to guide the Committee during review of informational items. This Worksheet is to be used to:

- Modify the protocol.
- Require additional follow-up with subjects.
- Modify eligibility criteria.
- Discontinue a treatment arm.
- Other.

Provide additional information to subjects:

1. Determine the subjects who should be informed:
   - Information is required as one or more of the elements of consent (21 CFR 50.25 or 45 CFR 46.116). No new subjects can be enrolled until a revised IRB-approved consent document is available.
   - Information could affect currently enrolled subjects willingness to continue in the study.
   - Information should be provided to past subjects.

2. Determine how subjects will be informed:
   - Inform currently enrolled subjects by asking them to sign a revised consent document.
   - Verbally tell currently enrolled or past subjects.
   - Inform currently enrolled or past subjects via IRB-approved letter.

3. Determine whether PI should be informed not to enroll subjects until s/he has obtained an IRB-approved consent document that includes all of the elements required by regulations. Yes ☐ No ☐

- Increase the frequency of continuing review.
- Observe the research or the consent process.
- Request a Quality Review.
- Require additional training.
  - Investigator training required on.
  - Staff training required on.
- Suspend IRB approval of enrollment.
- Suspend IRB approval of all study activities. Consider whether such suspension could result in harm to currently enrolled subjects.
- Terminate IRB approval. Consider whether such termination could result in harm to currently enrolled subjects.
- Table review and obtain additional information.
- Require Documentation:
  - New or revised SOP.
  - New or revised Checklist or Worksheet.
  - Other.
- Consider whether changes without prior IRB review were required to prevent imminent hazard to subjects or others. Yes ☐ No ☐.
<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-321</td>
<td>04.24.2019</td>
<td>2 of 2</td>
</tr>
</tbody>
</table>