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

- 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.
- Require a CAPA plan or a more robust CAPA plan.
- 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 ☐