UNIVERSITY OF MIAMI

WORKSHEET: Protection of Human Subjects During Review of Information

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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.

☐ 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