**WORKSHEET: New Information**

**Research Administration**

This worksheet is used to consider actions in response to new information determined to be one or more <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>.

1. **Considerations**
   - 1.1 Modify the protocol
   - 1.2 Modify the information disclosed during the consent process
   - 1.3 Modify the continuing review schedule
   - 1.4 Monitor the research
   - 1.5 Monitor the consent process
   - 1.6 <Suspend IRB Approval>
   - 1.7 <Terminate IRB Approval>
   - 1.8 Notify current subjects when such information may relate to subjects’ willingness to continue to take part in the research
   - 1.9 Provide additional information to past subjects
   - 1.10 Require current subjects to re-consent
   - 1.11 Refer to other organizational entities
   - 1.12 Make arrangements for medical care outside of a research study
   - 1.13 Transfer subjects to another investigator
   - 1.14 Have subject continue in the research under independent monitoring
   - 1.15 Have any adverse events or outcomes reported to the IRB
   - 1.16 Obtain additional information
   - 1.17 Require other actions

2. **Considerations to protect the rights and welfare of currently enrolled participants in suspended or terminated research**
   - 2.1 Allow some or all currently enrolled subjects to continue in the research because it is in their best interests
   - 2.2 Arrange for care outside the research
   - 2.3 Allow continuation of some research activities under the supervision of an independent monitor
   - 2.4 Require follow-up of subjects
   - 2.5 Require adverse events or outcomes to be reported to the IRB
   - 2.6 Notify current subjects
   - 2.7 Require other actions

3. **Notes**