1. **STUDY IDENTIFICATION**
   1. IRB#:
   2. Study Title:
   3. Principal Investigator:
2. **REVISIONS FROM PREVIOUS VERSION**
   1. None
3. **WHAT ACTIONS SHOULD BE CONSIDERED[[1]](#endnote-1)** 
   1. *General considerations*
      1. Modify the protocol
      2. Modify the information disclosed during the consent process
      3. Modify the continuing review schedule
      4. Monitor the research
      5. Monitor the consent process
      6. Suspend IRB Approval
      7. Terminate IRB Approval
      8. Notify current subjects when such information may relate to subjects’ willingness to continue to take part in the research
      9. Provide additional information to past subjects
      10. Require current subjects to re-consent
      11. Refer to other organizational entities
      12. Make arrangements for medical care outside of a research study
      13. Transfer subjects to another investigator
      14. Have subjects continue in the research under independent monitoring
      15. Have any adverse events or outcomes reported to the IRB
      16. Obtain additional information
      17. Require other actions
   2. *Considerations to protect the rights and welfare of currently enrolled participants in suspended or terminated research*
      1. Allow some or all currently enrolled subjects to continue in the research because it is in their best interests
      2. Arrange for care outside the research
      3. Allow continuation of some research activities under the supervision of an independent monitor
      4. Require follow-up of subjects
      5. Require adverse events or outcomes to be reported to the IRB
      6. Notify current subjects
      7. Require other actions
   3. *Other Actions:*

1. In response to an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, or Termination of IRB Approval [↑](#endnote-ref-1)