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)