AdventHealth Orlando

WORKSHEET: New Information

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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>.

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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