

HRP-321 | 2/2/2024

## **WORKSHEET: Review of Information Items**

The purpose of this worksheet is to provide support for the convened IRB reviewing <u>Serious Non-Compliance</u>, <u>Continuing Non-Compliance</u>, <u>Unanticipated Problem Involving Risks to Subjects or Others</u>, <u>Suspension of IRB Approval</u>, and <u>Termination of IRB Approval</u><sup>1</sup>.

## 1. Considerations

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<sup>&</sup>lt;sup>1</sup> This document satisfies AAHRPP elements I.5.A, I.5.D, I-9, II.2.G



Ш	Modify the protocol.
	Modify the information disclosed during the consent process.
	Provide additional information to current subjects (whenever the information may relate to the subject's willingness to continue).
	Provide additional information to past subjects.
	Have current subjects to re-consent.
	Increase the frequency of continuing review.
	Observe the research.
	Observe the consent process.
	Require additional training of the investigator.
	Notify investigators at other sites.
	Terminate IRB approval.
	Suspend IRB approval.
	Lift prior suspension of IRB approval.
	Transfer subjects to another investigator.
	Make arrangements for clinical care outside the research.
	Allow continuation of some research activities under the supervision of an independent monitor.
	Require follow-up of subjects for safety reasons.
	Require adverse events or outcomes to be reported to the IRB and the sponsor.
	Obtain additional information.
	Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.
	Other: Click or tap here to enter text.