

Interim/Event Report Review Checklist

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| **PI Name:**  | WMed IRB #:      *(for IRB office use only)* |
| Protocol Title:  |
| **Reviewer:**  | **Review Date:** Click or tap to enter a date. |

1. **Evaluation of Routine Reports**

Complete this section for evaluation of routine reports such as DSMB reports, monitoring reports, and audit reports.

* 1. Does the report suggest that subjects or others may be at more risk than was previously known or understood?

[ ]  Yes [ ]  No

Comments:

* 1. Does the report suggest that the research is not being conducted in accordance with the IRB-approved protocol/research plan, IRB requirements, or applicable regulations?

[ ]  Yes [ ]  No

Comments:

* 1. Does the report suggest that there may be other problems or issues with the research (e.g., feasibility, merit, futility, etc.)?

[ ]  Yes [ ]  No

Comments:

**If yes to a or b**, move on to **Section II**

**If yes to c**, move on to **Section III**

**If no to a, b, and c**, move on to **Section V**

1. **Evaluation of Potential Unanticipated Problems or Noncompliance**
	1. **Unanticipated Problems**

To qualify as an unanticipated problem involving risks to subjects or others, an event must meet the three criteria described below. If one or more of these criteria are answered NO, the event DOES NOT constitute an unanticipated problem involving risks to subjects or others. Events that may meet the definition of an unanticipated problem must be referred to the convened IRB for a final determination.

For additional information on Unanticipated Problems, consult the [WMed HRPP/IRB Handbook](http://med.wmich.edu/sites/default/files/HRPP%20IRB%20Handbook.pdf) or the following federal guidance documents:

* <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>
* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf>

**ANSWER EACH OF THE BELOW QUESTIONS**

* + 1. **Unexpected:** Is the incident, experience or outcome unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied?

[ ]  Yes [ ]  No [ ]  Unable to Determine

* + 1. **Related:** Is there a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research?

[ ]  Yes [ ]  No [ ]  Unable to Determine

* + 1. **Risk:** Does the event suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized?

[ ]  Yes [ ]  No [ ]  Unable to Determine

Based upon the above, does the event potentially meet the definition of an unanticipated problem involving risks to subjects or others as defined above (Yes to i, ii, and iii)?

 [ ]  YES, refer to convened IRB [ ]  No [ ]  Unable to Determine

Comments:

* 1. **Non-Compliance**

**Non-compliance** is defined as failure to adhere to federal, state, or local regulations governing human subject research, organizational policies related to human subject research, or the requirements or determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

Does the event meet the definition of non-compliance as defined above?

 [ ]  Yes [ ]  No [ ]  Unable to Determine

**If yes, answer each of the below questions**

* 1. Does the event potentially represent **serious non-compliance**? *Serious non-compliance is defined as non-compliance that, in the judgment of the convened IRB, creates an increase in risks to subjects, adversely affects the rights, welfare or safety of subjects, or adversely affects the scientific integrity of the study. Willful violation of regulations, policies, or procedures may also constitute serious non-compliance.*

[ ]  Yes, refer to convened IRB [ ]  No [ ]  Unable to Determine

Comments:

* 1. Does the event potentially represent **continuing non-compliance**? *Continuing non-compliance is defined as a pattern of non-compliance that, in the judgment of the convened IRB, suggests a likelihood that instances of non-compliance will continue unless the IRB or organization intervenes.*

[ ]  Yes, refer to convened IRB [ ]  No [ ]  Unable to Determine

Comments:

1. **Corrective and Preventative Actions (CAPA)**

* 1. Were corrective actions taken to mitigate risk or harm related to the event?

[ ]  Yes [ ]  No [ ]  NA

* + 1. If yes, were the corrective actions sufficient?

[ ]  Yes [ ] No

* 1. Were steps taken or proposed to prevent or minimize the likelihood of recurrence?

[ ]  Yes [ ] No [ ] NA

* + 1. Were/Are the preventative actions sufficient?

[ ]  Yes [ ] No

Comments:

1. **Subject Notification**
	1. Should subjects be notified or provided information about the event or issue? *(Consider whether the information could impact risks, benefits, procedures, participants’ willingness to continue in the study, etc.)*

[ ]  Yes [ ] No [ ] NA

Comments:

1. **Determinations**

[ ]  Approve/Acknowledge, the report is acceptable as submitted

[ ]  Conditions required for approval (e.g., prescriptive changes are needed to finalize approval/acknowledgement), conditions described below

[ ]  Defer for the reason(s) described below (e.g., additional information or non-prescriptive changes are needed)

[ ]  Refer to IRB Chair for immediate review (e.g., for possible suspension), reason described below

[ ]  Refer to convened IRB for review. (e.g., for evaluation of a possible unanticipated problem, or serious or continuing non-compliance), reason described below

Comments: