**Instructions to Principal Investigators:** Please use this form to document and work through a Root Cause Analysis (RCA) process in response to a reportable (or sentinel) event. You are encouraged to seek advice from Emory compliance and quality faculty and staff, as well as to consult the literature, for assistance in this process.

1. Submit your worksheet to the appropriate research compliance and quality offices at Emory University and Emory Healthcare.
2. Keep a copy of your worksheet in your research records.
3. Please consider every factor and if it does not apply in this instance, indicate “N/A” in the space provided rather than delete it or leave it blank.
4. As an aid to avoiding “loose ends,” the three columns on the right are provided to be checked off for later reference:
* “Root cause?” should be answered “yes” of “No” for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a “Why?” question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.
* “Asked Why?” should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn’t occur when it should have) – in other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a “Why?” question. It is expected that any significant findings that are not identified as root causes themselves have “roots,”
* “Action taken?” should be checked for any finding that can reasonably be considered for a corrective/preventive strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 3 in the “Action taken?” column for each of the findings that requires an action.

Need help? Please don’t hesitate to contact us:

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| --- | --- | --- | --- | --- | --- |
| Level of Analysis | **Questions** | **Findings** | **Root****Cause?** | **Ask****“Why?”** | **Take****Action** |
| What happened? | Sentinel Event | What are the details of the event? (Brief description) |  |  |  |  |
|  |  | When did the event occur? (Date, day of week, time) |  |  |  |  |
|  |  | What area/service was impacted? |  |  |  |  |
| Why did it happen? | The process or activity in which the event occurred. | What are the steps in the process, as designed? (A flow diagram may be helpful here) |  |  |  |  |
| What were the most proximate factors? |  | What steps were involved in (contributed to) the event? |  |  |  |  |
| (Typically “special cause” variation) | Human factors | What human factors were relevant to the outcome? |  |  |  |  |
|  | Equipment factors | How did the equipment performance affect the outcome? |  |  |  |  |
|  | Controllable environmental factors | What factors directly affected the outcome? |  |  |  |  |
|  | Uncontrollable external factors | Are they truly beyond the organization’s control? |  |  |  |  |
|  | Other | Are there any other factors that have directly influenced this outcome? |  |  |  |  |
|  |  | What other areas or services are impacted |  |  |  |  |

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| --- | --- | --- | --- | --- | --- |
| **Level of Analysis** | **Questions** | **Findings** | **Root****Cause?** | **Ask****“Why?”** | **Take****Action** |
| **Why did that happen? What systems and processes underlie those proximate factors?** | Human Resources issues | To what degree are staff properly qualified and currently competent for their responsibilities? |  |  |  |  |
| (Common cause variation here may lead to special cause variation in dependent processes) |  | How did actual staffing compare with ideal levels? |  |  |  |  |
|  |  | What are the plans for dealing with contingencies that would tend to reduce effective staffing levels? |  |  |  |  |
|  |  | To what degree is staff performance in the operant process (es) addressed? |  |  |  |  |

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| **Level of Analysis** | **Questions** | **Findings** | **Root****Cause?** | **Ask****“Why?”** | **Take****Action** |
|  |  | How can orientation and in-service training be improved? |  |  |  |  |
|  | Information management issues | To what degree is all necessary information available when needed? Accurate? Complete? Unambiguous? |  |  |  |  |
|  |  | To what degree is communication among participants adequate? |  |  |  |  |
|  | Environmental management issues | To what degree was the physical environment appropriate for the processes being carried out? |  |  |  |  |
|  |  | What systems are in place to identify environmental risks? |  |  |  |  |
|  |  | What emergency and failure-mode responses have been planned and tested? |  |  |  |  |
|  | Leadership issues:- Corporate culture | To what degree is the culture conducive to risk identification and reduction? |  |  |  |  |
|  | - Encouragement of communication | What are the barriers to communication of potential risk factors? |  |  |  |  |
|  | - Clear communication of priorities | To what degree is the prevention of adverse outcomes communicated as a high priority? How? |  |  |  |  |
|  | Uncontrollable factors  | What can be done to protect against the effects of these uncontrollable factors? |  |  |  |  |

See next page for Action Plan worksheet.

ACTION PLAN INSTRUCTIONS:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Corrective/Preventive Strategies | Measures of Effectiveness |  **Follow-up Log** |
|  | **Action Item #1:** |  |  |
|  | **Action Item #2:** |  |  |
|  | **Action Item #3:** |  |  |
|  | **Action Item #4:** |  |  |
|  | **Action Item #5:** |  |  |
|  | **Action Item #6:** |  |  |
|  | **Action Item #7:** |  |  |
|  | **Add Action Items as needed:** |  |  |
| **Cite any books or journal articles that were considered in developing this analysis and action plan:** |  |

Comments:

Reviewed by:

Date:

Disposition:

Reviewed by:

Date:

Disposition: