**IRB**

IRB File No.:

Date Received:

**Report of Non-Compliance Checklist**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Exploratory Committee Information** | | | | | | | | | | | | | | | | |
| IRB Chair/Co-Chair: | |  | | | | | EIU Department: | | | | | | |  | | |
| Tenured IRB Member: | |  | | | | | EIU Department: | | | | | | |  | | |
| Community Representative: | |  | | | | |  | | | | | | |  | | |
| Initial Convene Date: | |  | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | |
| **Protocol Information** | | | | | | | | | | | | | | | | |
| IRB Number: |  | Review Type: | | |  | | | IRB Review Date: | | | | | | |  | |
| Principal Investigator: | |  | | | | | | Department: | | | | | | |  | |
| Co-Invest./Faculty Sponsor: | |  | | | | | | Department: | | | | | | |  | |
| Additional Investigator(s): | |  | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | |
| **Incident Summary**  ***Briefly describe the incident(s)*** | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| **Interview/ Correspondence Information**  ***If there are additional interviewees, please include this information on a supplemental sheet.*** | | | | | | | | | | | | | | | | |
| Interviewee: |  | | | | | | | | Date: | |  | | | | |  |
| Interviewer(s): |  | | | | | | | | | | | | | | |  |
|  | | | | | | | | | | | | | | | | |
| In-Person | Written | | Report Info Only | | | Other: | | | |  | | | | | |  |
| **Notes:** | | | | | | | | | | | | | | | | |
| **Determination** | | | | | | | | | | | | | | | | |
| Upon discussion and review of the initial report and, when applicable, interview with the person alleging the issue, the exploratory committee has determined that:  There **is cause** to investigate the reported incident  There is **no cause** to investigate the reported incident | | | | | | | | | | | | | | | | |
| Rationale for determination: | | | | | | | | | | | | | | | | |
| Exploratory committee chair signature: | | | |  | | | | | | | |  | Date: | |  |  |
| If cause has been determined, continue with checklist on the next page. | | | | | | | | | | | | | | | | |

**Investigation of Non-Compliance**

Completed report will be presented and discussed at the next regular IRB meeting unless the investigative committee determines the issue is serious enough to be considered before the meeting. A copy of this report will be kept on file in the Office of Research and Sponsored Programs

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Investigative Committee Information** | | | | | | | | | | | | | | | |
| IRB Chair/Co-Chair: | | | |  | | | | EIU Department: | | | | | |  | |
| Tenured IRB Member: | | | |  | | | | EIU Department: | | | | | |  | |
| Community Representative: | | | |  | | | |  | | | | | |  | |
| Initial Convene Date: | | | |  | | | | | | | | | | | |
|  | | | |  | | | | | | | | | | | |
| **Researcher Notification** | | | | | | | | | | | | | | | |
| The investigative committee chairperson must notify the researcher/PI in writing within 5 business days of determination of cause that an allegation of non-compliance has been received. | | | | | | | | | | | | | | | |
| Person(s) Notified: | | |  | | | | | | | | | | | | |
| Date: | | |  | | | | In writing via: | | |  | | | | | |
|  | | | |  | | | | | | | | | | | |
| **Researcher Interview/Correspondence Information**  ***If there are additional interviewees, please include this information on a supplemental sheet.*** | | | | | | | | | | | | | | | |
| Interviewee: |  | | | | | | | | Date: | | |  | | |  |
| Interviewer(s): |  | | | | | | | | | | | | | |  |
|  | | | | | | | | | | | | | | | |
| In-Person | | Written | | | Other: |  | | | | | | | | |  |
| **Notes:** | | | | | | | | | | | | | | | |
| The investigative committee will produce written summaries to the interviewed parties for comments, and written comments received will be included in the record of the investigation. | | | | | | | | | | | | | | | |
| **Written summary sent to researcher (date):** | | | | | |  | | | | | Sent by: | |  | |  |
| Upon completion of the interview, the investigative committee can require changes to the protocol if necessary, and resolve without further official action. In this case, complete only the Further Action section below and submit to ORSP. | | | | | | | | | | | | | | | |
| **Additional Information** | | | | | | | | | | | | | | | |
| Provide detail regarding any records, data, or other records provided to the investigative committee by the researcher or other parties, including who the information was obtained from. | | | | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Findings** | | | | | | | | |
| Allegation of non-compliance is | | | | | | | | |
| Founded | | Unfounded | Other: |  | | | |  |
| Basis for findings: | | | | | | | | |
| **Further Action** | | | | | | | | |
| Investigative committee members will consider potential of risk or impact to participants, researchers, and/or the University, and/or previous violations by researcher when determining the recommended action(s).  **Recommended IRB Action:**  No action  Protocol requires modification to be reviewed by investigative committee member  Study should be monitored (frequency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )  Study should be suspended  Unacceptable and uncorrectable levels of risk or harm to the subjects or others exist or serious disregard on the part of the researcher to the policies and directives of the IRB has occurred.  Study should be terminated  Unacceptable and uncorrectable levels of risk or harm to the subjects or others exist or serious disregard on the part of the researcher to the policies and directives of the IRB has occurred. | | | | | | | | |
| Other: |  | | | | | | |  |
| Comments/Rationale: | | | | | | | | |
| investigative committee chair signature: | | |  | |  | Date: |  |  |
|  | | | | | | | | |
| **Additional Comments:** | | | | | | | | |