**Instructions to the Investigator**:

The following problems must be reported to the IRB within 48 hours using this form:

* Any harm experienced by a participant, which in the opinion of the principal investigator are both unexpected and related to the research procedures.
  + Harm is “unexpected” when its specificity and severity are not accurately reflected in the consent document.
  + Harm is “related to the research procedures” if in the opinion of the principal investigator, it is more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.
    - Information that indicates a change to the risks or potential benefits of the research.

*For Example:*

* + - * An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the IRB.
      * A paper is published from another study that shows that the risks or potential benefits of your research might be different from those initially presented to the IRB.
        + A breach of confidentiality.
        + Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
        + Incarceration of a participant in a protocol not approved to enroll prisoners.
        + An event that required prompt reporting to the sponsor.
        + Sponsor imposed suspension for risk.
        + Complaint of a participant.
        + Protocol deviation.

Upon any adverse event occurring during a research study, the principal investigator MUST complete section I and submit this form within 48 hours and email to the IRB Chair at [IRB@methodistcollege.edu](mailto:IRB@methodistcollege.edu). Upon receipt, the IRB Chair should review the report and take appropriate action to include immediately giving a copy of the NMC Compliance Director.

**Section I - *To be completed by investigator***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Principal Investigator:** | | | | |  | | | | | | | | | |
| **Department/Program:** | | |  | | | | | | | **Phone :** | |  | | |
| **Email Address:** | |  | | | | | | | | | | | | |
| **Co-Principal/Secondary Investigator:** | | | | | | | |  | | | | | | |
| **Department/Program:** | | |  | | | | | | | **Phone :** | |  | | |
| **Email Address:** | |  | | | | | | | | | | | | |
| **Research Title:** | |  | | | | | | | | | | | | |
| **IRB #:** |  | | | | | | **IRB Approval Date:** | | | |  | | | |
| **Date of Adverse Event:** | | | |  | | | | | **Date first known to Investigator:** | | | |  |
| **Subject’s ID (if available)** | | | | | |  | | | | | | | |

**EVENT INFORMATION:**

1. Describe in detail the nature of the adverse event:
2. Describe the impact on subject(s):
3. Describe corrective action taken: (*Check all that apply*)

Stopped enrollment of new subjects. Provide explanation:

Halted the study. Provide explanation:

Changed data management/coding procedures. Provide explanation:

Changed confidentiality and privacy protection procedures

Provide explanation:

Other (*please specify*):

Provide explanation:

|  |  |  |  |
| --- | --- | --- | --- |
| **Signature of Principal Investigator** (*required*)**:** |  | **Date:** |  |

**Section II – *To be completed by the NMC IRB Chair***

1. The adverse event appears to: (*check one from each row*)

Be anticipated  NOT be anticipated

Involve risks to subjects or others  Involve NO risks to subjects or others

Involve non-compliance  NOT involve non-compliance

* 1. The event is (1) not anticipated and (2) involves risk to subjects or others  **Yes  No**

If yes, submit report for full IRB review as an unanticipated problem involving risks to subjects or others (*see NMC IRB Handbook*). Have investigator make appropriate changes and submit to the IRB for review.

* 1. The event involves non-compliance  **Yes  No**

If yes, handle under the Non-compliance Policy (*see CFR Title 45, Part 46, §46.103*)

* 1. If neither (a) or (b), no further action is needed.

1. Was this non-compliance or breach of confidentiality caused by serious or continuing non-compliance?  **Yes  No**

If yes, then a letter must be sent by the HRPP Director informing regulatory agencies and institutional officials.

1. Describe actions taken by the convened IRB (*if applicable*):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IRB Chair** | | | | |
| **Printed Name:** | |  | **Date:** |  |
| **Signature**: |  | | | |

**Remarks:**