Monmouth University

Human Research Protection Program/Institutional Review Board Office

**Interim/Event Report Submission Form**

This form should be used for the submission of interim reports to the Monmouth University IRB. Reporting requirements are detailed in the Monmouth University HRPP/IRB Manual and include, but are not limited to, event reports such as protocol deviations, unanticipated problems, subject complaints, and potential noncompliance in study activities.

Unless specifically required by the IRB, the IRB does not accept reports of adverse events that do not meet the definition of an unanticipated problem involving risks to subjects or others (UAP).

If investigators are uncertain but believe that an event or issue might meet the definition of an UAP, a report should be submitted along with an analysis by the sponsor or investigator.

1. **PROTOCOL INFORMATION**

|  |  |
| --- | --- |
| PI Name: | IRB Number: |
| Protocol Title: | |
| Faculty Supervisor (if PI is a student): | |

1. **DEFINITIONS**

**Incarceration.**  Individuals are incarcerated when they are involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Noncompliance** is defined as the failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, or the requirements or determinations of the IRB. Noncompliance may be minor or sporadic or it may be serious or continuing.

**Protocol Deviation** means any variation from the IRB approved research plan that happens without prior review and approval of the IRB and that isn’t necessary to eliminate apparent immediate hazards to the subject(s).

**Unanticipated problems involving risk to participants or others (UAP)**refers to any incident, experience, outcome, or new information that:

1. Is unexpected; **and**
2. Is at least possibly related to participation in the research; **and**
3. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized

Additional information regarding UAPs, including several examples, is available in the Monmouth University HRPP SOPs.

**Unexpected,** as it relates to unanticipated problems, means that the incident, experience or outcome is not expected (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.

1. **TYPE OF REPORT**

|  |  |
| --- | --- |
|  | 1. Audit or inspection report |
|  | 1. Change in PI availability or ability to conduct or supervise the study |
|  | 1. Change made to the research without prior IRB approval to eliminate an apparent immediate hazard to the subject(s) |
|  | 1. Change that impacts the qualifications of investigators/staff (e.g., actions taken by regulatory authorities, licensing boards, credentialing committees) |
|  | 1. Data Safety Monitoring report (e.g., DSMB, DMC, etc.) |
|  | 1. Hold, suspension, or termination of a study or certain study activities by an investigator, sponsor, or others |
|  | 1. Incarceration of a subject in a protocol not approved for enrollment of prisoners |
|  | 1. Other change in vulnerable populations (e.g., enrollment or inclusion of vulnerable populations without prior IRB approval, or when an existing subject becomes a member of a vulnerable population when the study does not have prior IRB approval for inclusion of the vulnerable population) |
|  | 1. Known or potential issue impacting subject privacy or confidentiality (e.g., lost laptop) |
|  | 1. Known or potential noncompliance |
|  | 1. Known or suspected Unanticipated Problem Involving Risks to Subjects or Others (UAP) |
|  | 1. New information that indicates a change to the risks or potential benefits of the research. Examples include:  * an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB * a paper is published from another study that shows that the risks or potential benefits of the research may be different than initially presented to the IRB. |
|  | 1. New information that may impact the health, rights, welfare, or willingness of subjects to continue in the research |
|  | 1. Protocol deviation report |
|  | 1. Routine monitoring report |
|  | 1. Sponsor or coordinating center report |
|  | 1. Subject complaint |
|  | 1. Other, describe: |

1. **EVENT/REPORT DESCRIPTION**
   1. Date of Occurrence:
   2. Date you became aware of occurrence or received report:
   3. Description of issue, event, or report:

1. **ADDITIONAL INFORMATION**

|  |
| --- |
| Complete this section UNLESS you are reporting:   * **Routine reports** such as monitoring reports, sponsor/coordinating center reports, updated product information, or DSMB reports with no issues identified or changes recommended. A copy of the report should be included with the submission of this report form. * **Audit or inspection reports**. A copy of the report and any related correspondence should be included with the submission of this report form. Any corrective actions or other information relevant to the report should be described above or included in a memo. * **Reports of changes made to the research without prior IRB approval to eliminate an apparent immediate hazard to the subject(s**). Detail for these issues, including the reason the change was made, why prior IRB approval was not possible, any potential impact of the change on the subject or the study (e.g., inclusion, analysis, or reporting of data), and any other relative information should be described above or in an attached memo. * **Reports of issues impacting the PI’s availability or the qualifications of investigators or staff**. Detail for these, including relevant dates and any plans for management or resolution should be included in the description above or in an attached memo. |

1. Did the event or problem involve subjects in the study locally?  Yes  No

If Yes, provide Subject ID:

If No, indicate if other individual(s) were involved and how?

1. Was the event **Unexpected** (in terms of nature, severity, or frequency)?  Yes  No

Explain:

1. Was the event **Related** or possibly related to participation in the research?  Yes  No

Explain:

1. Does the event or issue suggest that the research places subjects or others at a **Greater Risk of Harm** (including physical, psychological, economic, or social harm) than was previously known or recognized? ☐ Yes ☐ No

Explain:

1. Did the event or issue cause **actual harm** to subjects or others?  Yes  No

If yes, provide a detailed description of any harms that occurred and any actions in response:

1. Did the event or issue present the possibility that there may be delayed harm/negative affect to subjects or others?  Yes  No

If yes, provide a detailed description of possible delayed harms and actions taken to mitigate those harms:

1. Did the event or issue otherwise affect the rights, safety, or welfare of the subjects?  Yes  No

If yes, explain:

1. Does the event or issue affect the integrity of the study (e.g., data integrity)?  Yes  No

If yes, explain:

1. Describe the root cause of the event or issue and any corrective actions to mitigate risk or harm and any actions that will be taken to prevent its recurrence. If the protocol and/or consent are to be modified submit a Modification Request (Amendment).

1. Do currently enrolled subjects or others require notification?  Yes  No

If yes, describe your planned method of communication and submit any materials to be used for this purpose:

1. Provide any other information that could be of importance to the IRB in its review:

**Attach any additional relevant documentation to this submission.**

1. **SIGNATURES**

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Investigator Signature Date

**IF THE INVESTIGATOR IS A STUDENT, A FACULTY ADVISOR/DEPT CHAIR/DEAN/DIRECTOR MUST SIGN BELOW**  N/A

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Faculty Advisor Signature Date