**Interim/Event Report Form**

This form should be used for the submission of interim reports to the NJH IRB. Reporting requirements are detailed in the NJH HRPP/IRB SOPs and include, but are not limited to, and event reports such as protocol deviations and unanticipated problems that involve subject safety, subject complaints, potential serious and continuing noncompliance, and suspensions of study activities.

Note: Adverse events in clinical trials must be reported to the sponsor in compliance with FDA regulations and sponsor requirements. Unless specifically required by the IRB (e.g., the IRB might request such reports for a first in human clinical trial), the NJH HRPP/IRB does not accept reports of adverse events and IND Safety Reports that do not meet the definition of an unanticipated problem involving risks to subjects or others (UPIRTSO).

NJH HRPP/IRB does not require reporting a Protocol Deviation unless it involves risk to subjects or compromises data integrity.

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

1. **PROTOCOL INFORMATION**

|  |  |
| --- | --- |
| PI Name:  | IRB Number:  |
| Protocol Title:  |

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** is a kind of Noncompliance. Protocol Deviation means any variation from the IRB approved research plan that happens without prior review and approval of the IRB.

**Serious Non-Compliance:** Protocol deviation that, in the preliminary opinion of the NJH Investigator, increases risk to subjects, impacts rights & welfare, causes harm or compromise data integrity. Examples include:

* Enrollment or continued inclusion of vulnerable populations without prior IRB approval
* Conducting non-exempt human subjects research without IRB approval
* Conducting non-exempt human subjects research without obtaining informed consent, without an IRB-approved waiver of informed consent

**Continuing Non-Compliance:** Same deviation(s) continue after initial discovery, reporting and corrective action plan have been implemented to either specific or multiple protocols

**Unanticipated adverse device effect (UADE)** means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

**Unanticipated problems involving risk to participants or others (UPIRTSO)**refers to any incident, experience, outcome, or new information, that in the preliminary opinion of the NJH Investigator:

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

UPIRTSOs can be both local or at another site participating in the same protocol.

Additional information regarding UPIRTSOs, including several examples, is available in the NJH HRPP/IRB SOPs at section 18.

**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.) if involves change to risk/benefit or raises safety issues
 |
| [ ]  | 1. Hold, suspension, or termination of a study or certain study activities by an investigator, sponsor, or others
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| [ ]  | 1. Incarceration of a subject in a protocol not approved for enrollment of prisoners
 |
| [ ]  | 1. Known or potential issue impacting subject privacy or confidentiality (e.g., lost laptop)
 |
| [ ]  | 1. Known or potential Serious Noncompliance: Protocol deviation that, in the preliminary opinion of the NJH Investigator, increases risk to subjects, impacts rights & welfare, caused harm or compromised data integrity
 |
| [ ]  | 1. Known or potential Continuing Noncompliance: Same deviation(s) continues after initial discovery, reporting and corrective action plan have been implemented to either specific or multiple protocols
 |
| [ ]  | 1. Known or suspected Unanticipated Adverse Device Effect (UADE)
 |
| [ ]  | 1. Known or suspected Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) that in the preliminary opinion of the NJH Investigator:
* Is unexpected; **and**
* Is at least possibly related to participation in the research; **and**
* 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
 |
| [ ]  | 1. New information that indicates a change to the risks or potential benefits of the research. Examples include:
* an interim analysis 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.
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| [ ]  | 1. New information that may impact the health, rights, welfare, or willingness of subjects to continue in the research
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| [ ]  | 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**

|  |
| --- |
| Unless requested by the IRB, the questions in this section **do not** have to be completed for:* **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.
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1. Study Drug/Device Name:  [ ]  NA
2. 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 any corrective actions to mitigate risk or harm related to the event or issue and any actions that will be taken to prevent its recurrence (CAPA plan). 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 FELLOW, A FACULTY ADVISOR/DEPT CHAIR/DEAN/DIRECTOR MUST SIGN BELOW** [ ]  NA

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