

**Interim/Event Reporting Form**

Investigators should use this form for interim reports to the Western Michigan University Homer Stryker M.D. School of Medicine (WMed) IRB. Reporting requirements are detailed in the WMed HRPP and IRB Handbook and include, but not limited to, routine reports such as sponsor monitoring reports and event reports such as protocol deviations, unanticipated problems, and suspensions of study activities by the investigator, sponsor, or coordinating center.

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 first in human clinical trials), the WMed 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.

If investigators are uncertain but believe that the adverse event might qualify as an unanticipated problem, a report should be submitted.

1. **PRINCIPAL INVESTIGATOR AND RESEARCH TEAM**
   1. **Principal Investigator**

|  |  |
| --- | --- |
| **PI Name:** | **Date:** Click here to enter a date. |
| Protocol Title: | WMed IRB #:  *(for IRB office use only)* |

|  |  |
| --- | --- |
| Faculty  Other: | Department/Unit: |
| Address: | |
| Email: | Phone Number: |

1. **DEFINITIONS**

**Unanticipated problems involving risk to participants or others*.*** Unanticipated problems involving risks to participants or others (UAPs) refer to any incident, experience, outcome, or new information that:

1. Is unexpected (The incident, experience or outcome is not expected in terms of nature, severity, for 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;
2. Is related or possibly related to participation in the research (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved 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.

**Protocol Deviation.** A protocol deviation is defined as a variation from the IRB-approved research plan that happens without prior review and approval of the IRB (e.q., study visit scheduled outside protocol/research plan window, blood work drawn outside protocol/research plan window, etc.).

**Non-compliance.** Non-compliance is defined as failure to adhere to federal, state, or local regulations governing human subject research, organizational policies related to human subject research, or the requirements or determinations of the IRB.

**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.

**Unanticipated adverse device effect.** 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*.*

1. **TYPE OF REPORT**

Investigators must report the following events or issues to the IRB as soon as possible, but in no event later than seven working days after the investigator first learns of the event.

|  |  |
| --- | --- |
|  | 1. A single occurrence of a serious, unexpected event that is uncommon and strongly associated with drug exposure (such as angioedema, agranulocytosis, hepatic injury, or Stevens-Johnson syndrome). |
|  | 1. A single occurrence, or more often a small number of occurrences, of a serious, unexpected event that is not commonly associated with drug exposure, but uncommon in the study population (e.g., tendon rupture, progressive multifocal leukoencephelopathy.) |
|  | 1. Multiple occurrences of an AE that, based on an aggregate analysis, is determined to be an unanticipated problem. There should be a determination that the series of AEs represents a signal that the AEs were not just isolated occurrences and involve risk to human subjects (e.g., a comparison of rates across treatment groups reveals higher rate in the drug treatment arm versus a control). A summary and analyses supporting the determination should accompany the report. |
|  | 1. An AE that is described or addressed in the investigator’s brochure, protocol, or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations. For example, if transaminase elevation is listed in the investigator’s brochure and hepatic necrosis is observed in study subjects, hepatic necrosis would be considered an unanticipated problem involving risk to human subjects. A discussion of the divergence from the expected specificity or severity should accompany the report. |
|  | 1. A serious AE that is described or addressed in the investigator’s brochure, protocol, or informed consent documents, but for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence (ordinarily, reporting would only be triggered if there were a credible baseline rate for comparison). A discussion of the divergence from the expected rate should accompany the report. |
|  | 1. Changes made to the research without prior IRB approval to eliminate apparent immediate hazards to the subject(s). |
|  | 1. Adverse events involving direct harm to subjects enrolled by the investigator (i.e., local adverse events), which in the opinion of the investigator or sponsor, may represent an unanticipated problem involving risk to subjects or others. |
|  | 1. An unanticipated event related to the research that exposes subjects to potential risk but that does not involve direct harm to subjects (e.g. lost laptop). |
|  | 1. An unanticipated event related to the research that result in actual harm or exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk. |
|  | 1. IND Safety Reports from sponsors that meet the criteria for an unanticipated problem involving risk to subjects. |
|  | 1. Data and Safety Monitoring Reports that indicate that risks are greater than previously known or that indicate that the study requires modification or should be suspended or terminated. |
|  | 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 willingness of participants to continue in the research. |
|  | 1. A breach of confidentiality |
|  | 1. Incarceration of a participant in a protocol not approved to enroll prisoners |
|  | 1. Complaint of a subject when the complaint involves the indicates unexpected risks or cannot be resolved by the research team |
|  | 1. Protocol/research plan deviations. |
|  | 1. Sponsor or lead investigator/coordinating center imposed suspension or termination of some or all research activities. |
|  | 1. Unanticipated adverse device effect (UADEs). (Note: Regulations require that UADEs be reported to the sponsor and IRB as soon as possible but in no event later than 10 working days after the investigator first learn of the event [21 CFR 812.150(a)(1)]). |
|  | 1. Any other adverse event or safety finding (e.g. based on animal or epidemiologic data) that indicates subjects or others might be at risk of serious, unanticipated harms that are reasonably related to the research. These would cause the sponsor to modify the investigator’s brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects. An explanation of the conclusion should accompany the report. |
|  | 1. Routine Study Monitoring Report |
|  | 1. Audit or Inspection Report |
|  | 1. Other |

1. **DESCRIPTION OF EVENT OR REPORTABLE ISSUE** (*This section is not required for routine reports such as monitoring reports, DSMB reports with no changes recommended, etc.)*
   1. Date of Occurrence: Click here to enter a date.
   2. Date you became aware of occurrence:
   3. Study Drug/Device:   N/A
   4. Describe the event or problem and its relationship to study design, safety, and/or data. (e.g. loss of confidentiality, increased risk and/or harm).

* 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 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 problem 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 problem 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. Describe any corrective actions to mitigate risk or harm related to the event 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 Request for Modification (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.

Re-Consent will occur at the subjects next scheduled visit

Subject will be called at home

Subject will be sent a text message (SMS)

Subject will be contacted via social media (i.e. Twitter, Facebook, Second Life, or other virtual means)

Subject will be sent an email

A letter will be mailed to the subject’s home (a copy of the letter must be included with this submission.)

Other:

* 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. **PRINCIPAL INVESTIGATOR STATEMENT OF ASSURANCE**

I certify that the information provided in this application is complete and correct.

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Signature of Principal Investigator Date