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| **WORKSHEET: Prompt Reporting Review**  \*Please note name change from Worksheet: New Information\* | | | |
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| --- | --- |
| PI Name: | IRB Number: |
| Protocol Title: | |
| Reviewer: | Date: |

# Reviewer COI

1. Do you have any interests, financial or otherwise, related to this submission that could present a conflict of interest?

Yes. Please do not conduct this review, contact the IRB office so that the submission can be reassigned.

No

# Evaluation of Potential Unanticipated Problems or Noncompliance

1. **Unanticipated Problems**

To qualify as an unanticipated problem involving risks to subjects or others (UPIRSO), an event or issue must meet the three criteria described below. If one or more of these criteria are answered NO, the event DOES NOT constitute an UPIRSO. Events or issues that may meet the definition of an UPIRSO must be referred to the convened IRB for a final determination.

For additional information on UPIRSOs, consult the DrexelHRPP/IRB Policy 071 Prompt Reporting Requirements and the following federal guidance documents:

* OHRP Guidance: [Unanticipated Problems Involving Risks & Adverse Events](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html)
* FDA Guidance: [Adverse Event Reporting to IRBs — Improving Human Subject Protection](https://www.fda.gov/media/72267/download)
* FDA Guidance: [Safety Reporting Requirements for INDs and BA/BE Studies](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-reporting-requirements-inds-investigational-new-drug-applications-and-babe)
  1. **Unexpected:** Is the issue unexpected (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?

Yes  No  Unable to determine

Comments:

* 1. **Related:** Is the event related or possible related to participating in the research?

Yes  No  Unable to determine

Comments:

* 1. **Risk:** Does the issue suggest that subjects or others are at greater risk of harm than was previously known or recognized?

Yes  No  Unable to determine

Comments:

* 1. Based upon the above, does the issue potentially meet the definition of a UAP (Yes to a, b, & c)?

Yes  No  Unable to determine

Comments:

1. **Possible Unanticipated Adverse Device Effect**

NA – **The report does not involve a medical device, # 3.**

An 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 previous 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 related to the rights, safety, or welfare of subjects [[21 CFR 812.3(s)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.3)].

**Answer the following:**

* + 1. Is the report indicative of any of the following?  Yes  No  Unable to determine

Serious adverse effect on health

Serious adverse effect on safety

Life-threatening problem

Death

Other serious problem that relates to the rights, safety, or welfare of subjects

Comments:

* + 1. Is there a reasonable possibility that the effect, problem, or outcome may have been caused by or associated with a medical device?

Yes  No  Unable to determine

Comments:

* + 1. Is the effect, problem, or outcome unexpected? (i.e., is the nature, severity, or degree of incidence of the effect, problem, or outcome inconsistent with what is already known about the device as described in the protocol, instructions for use, or other materials?)

Yes  No  Unable to determine

Comments:

* + 1. Based upon the above, is the effect, problem, or outcome an UADE (Yes to i, ii, and iii)?

Yes, UADEs must be immediately reported by the investigator to the sponsor for evaluation and by the sponsor (or sponsor-investigator) to the FDA (within 10 working days of notice). Contact the IRB office to inform them of this determination and the need to immediately inform the investigator. This determination should be reported to the convened IRB and the IRB should determine if any additional actions are warranted.

No

Unable to determine

Comments:

1. **Noncompliance**

Noncompliance is defined as any failure to follow:

* Applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or
* The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).

Noncompliance can result from performing an act that violates these requirements or failing to act when required. Noncompliance may be minor or sporadic or it may be serious or continuing.

Issues or events that may represent serious or continuing noncompliance must be referred to the convened IRB for a final determination.

* 1. Does the issue or event described in the report meet the definition of noncompliance (above)?

Yes  No  Unable to determine

Comments:

**If Yes, answer the following:**

* + 1. Does the issue or event described in the report potentially represent serious noncompliance? *Serious noncompliance is defined as noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare, of subjects; or adversely affects the integrity of the data or the research.*

Yes  No  Unable to determine

Comments:

* + 1. Does the issue or event described in the report potentially represent continuing noncompliance? *Continuing noncompliance is defined as a pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe.*

Yes, refer to convened IRB  No  Unable to determine

Comments:

# Corrective and Preventative Actions (CAPA)

1. Were corrective actions taken to mitigate risk or harm related to the issue or event?

Yes  No

* 1. If Yes, were the corrective actions sufficient?

Yes  No

1. Were steps taken or proposed to prevent or minimize the likelihood of recurrence?
   1. If Yes, were/are the preventative actions sufficient?

Yes  No

Given the circumstances, the IRB may take any of the following actions, or others, to ensure the protection of human subjects, should any of the following be considered in addition to the corrective and preventive action plan provided by the PI/study team:

Requiring modifications to the protocol or plan or procedures for implantation of the research (Research Plan) as described in the application and other materials submitted to the IRB;

Revising the continuing review timetable;

Modifying the consent process;

Modifying the consent document;

Requiring additional training of the investigator and/or study staff;

Requiring that current subjects re-consent to participation;

Monitoring the research, or similar research in nature, study personnel, or as otherwise recommended by the IRB, HRPP, or other compliance offices.;

Monitoring consent;

Reporting or referral to appropriate parties (e.g., the IO, Research Integrity Officer, Legal, Conflict of Interest, Privacy);

Suspending IRB approval;

Terminating IRB approval;

Other actions as appropriate given the specific circumstances.

Comments:

# Subject Notification

1. Should subjects be notified or provided information about the issue or event?  *(Consider whether the information could impact risks, benefits, procedures, subjects’ willingness to continue in the study, etc.)*

Yes  No  NA

If no or NA, include the reasoning, if yes consider the population, current enrollment status, the risk, timeline and notification mechanism when providing a notification plan(e.g., all subjects currently receiving study drug, through a consent addendum, prior to their next infusion):

# RECOMMENDED DETERMINATIONS

**The issue, event, or new information described in the report represents in the best judgement of the reviewer in preparation for the full board (check all that apply):**

UPIRSO

An UADE, immediately inform the investigator of the determination and their reporting obligations.

Noncompliance

Serious Noncompliance

Continuing Noncompliance

Information that must be reported to AAHRPP[[1]](#endnote-1) *(Please inform the HRP Director immediately)*

None of the above

Comments:

1. Prompt reporting (asap but generally within 48 hours of awareness) to AAHRPP is required for:

   1. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
   2. Any litigation, arbitration, or settlements initiated related to human research protections.
   3. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization’s HRPP

   [↑](#endnote-ref-1)