ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Recording and Reporting of Adverse Events for Research Protocols

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APBMT-COMM-030
RECORDING AND REPORTING OF ADVERSE EVENTS FOR RESEARCH PROTOCOLS

1 PURPOSE

1.1 To identify and report adverse events (AE) in a timely manner in order to ensure patient safety and to be compliant with requirements of regulatory agencies and research protocol requirements.

2 INTRODUCTION

2.1 In order to protect patients and minimize the risk of injury, reporting of all unexpected serious, study related adverse events associated with participating in a clinical trial must be recognized and reported to Duke University Institutional Review Board (IRB) per the IRB’s requirements. Industry-sponsored studies may have additional reporting requirements to the sponsor, IRB and/or the Food and Drug Administration.

2.1 Adverse Events: Any unintended or unfavorable sign, symptom, abnormality, or condition temporarily associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse events are documented by the clinicians and graded by the research teams using Common Terminology Criteria for Adverse Events (CTCAE) per protocol. All adverse events reported or observed during the study beginning at the time of enrollment must be recorded. Information to be reported includes when the site became aware of the event, investigator-specified assessment of severity and relationship to study therapy, whether there is an alternative etiology, seriousness, as well as any required treatment or evaluations, and outcome. In general, investigators should report adverse events as diseases or syndromes whenever possible, instead of reporting individual component symptoms, signs, laboratory abnormalities, and sequelae.

2.2 Unexpected Serious Adverse Event (SAE):

2.2.1 Unexpected and study related SAE’s are to be reported within 24 hours of their discovery to the sponsor on sponsored studies. SAE is any event which:

2.2.1.1 Is fatal

2.2.1.2 Is life threatening

2.2.1.3 Is permanently/significantly disabling

2.2.1.4 Requires or prolongs hospitalization

2.2.1.5 Causes a congenital anomaly

2.2.1.6 Requires intervention to prevent impairment or damage

2.3 Unexpected Serious Adverse Events are to be recorded in the Access database (adult) or manually (peds) and on the case report form according to protocol-
specific guidelines if provided by the sponsor or on a MedWatch form if this is not a sponsored trial. The SAE report is sent to the IRB if it meets their requirements for reporting or if the protocol requires it.

Unexpected and study related Serious Adverse Events (SAE) should be reported to the IRB and/or sponsor electronically, via telephone or fax within 24 hours. Every study-related death within 30 days of being on a clinical trial is reported to the IRB. Serious or unexpected events associated with the use of an investigational product must be reported to the FDA within 15 calendar days or per the sponsor’s requirement. Events which are fatal or life-threatening, unexpected and study related must be reported to FDA within 7 calendar days for studies under IND.

3 SCOPE AND RESPONSIBILITIES

3.1 Physicians and Research Staff working within the Divisions of Hematologic Malignancies and Cellular Therapy and Pediatric Blood and Marrow Transplantation (PBMT) have a responsibility to ensure that all adverse events are reported in a timely fashion.

4 DEFINITIONS/ACRONYMS

4.1 AE Adverse Event
4.2 CTCAE Common Terminology Criteria for Adverse Events
4.3 FDA Food and Drug Administration
4.4 IRB Institutional Review Board
4.5 PBMT Pediatric Blood and Marrow Transplant
4.6 SAE Serious Adverse Event

5 MATERIALS

5.1 MedWatch form
5.2 Sponsor provided forms (if applicable)

6 EQUIPMENT

6.1 Computer

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Study specific procedures and guidelines will be followed for adverse event reporting. Guidelines are detailed below.
8.1.1 Most industry-sponsored or cooperative group trials have specific forms which are to be used to report adverse events and serious adverse events. The protocol document, regulatory binder, and case report forms contain protocol-specific requirements and instructions for reporting adverse events.

8.1.2 Duke University sponsored trials will have MedWatch forms completed for serious adverse events. All adverse events will be documented on toxicity forms and entered into the Cellular Therapy data base by the adult team. PBMT clinicians will document toxicities in the clinical notes.

8.1.3 Complete the case report form or serious adverse event form provided by the sponsor with all pertinent information available at the time the SAE is first noted. If no such form is provided by the sponsor, complete a MedWatch form. MedWatch forms may be downloaded from the FDA web site at www.fda.gov/medwatch. To meet the reporting timelines, the form may need to be submitted before all information is gathered. If this is the case, complete the form with all currently known information regarding the SAE and submit the form. If new information becomes available, a follow-up report should be submitted within 15 days of becoming aware of new information.

8.1.4 Serious adverse events are reported internally through the Cellular Therapy or PBMT Clinical Research Coordinators. The Clinical Research Coordinator will notify the Duke Cancer Center and Institutional Review Board as well as regulatory agencies, when applicable.

8.1.5 Transplant product infusion adverse events and reactions and product complaints will be reported to the National Marrow Donor Program through CIBMTR/formsnet per their requirements.

9 RELATED DOCUMENTS/FORMS
9.1 NA

10 REFERENCES
10.2 U.S. Food and Drug Administration – www.fda.gov/medwatch
11 REVISION HISTORY

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<th>Author</th>
<th>Description of Change(s)</th>
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<tr>
<td>07</td>
<td>Jennifer Frith</td>
<td>The definition of adverse event has been updated to be consistent across internal SOPs and FACT guidance.</td>
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<td>Section 8.1.3 updated to clarify submission of 15 day follow-up reports.</td>
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# Signature Manifest

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All dates and times are in Eastern Time.

## APBMT-COMM-030 Recording and Reporting of Adverse Events for Research Protocols

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