Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Third Party Agreement

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COMM-PAS-001
THIRD PARTY AGREEMENT

1 PURPOSE

1.1 The purpose of this procedure is to describe how the Adult and Pediatric Blood and Marrow Transplant Programs (APBMT) and the Stem Cell Laboratory (STCL) develop third party agreements with entities whose services impact the cellular therapy product.

2 INTRODUCTION

2.1 It is good practice and required by standards to have a controlled method of developing third party agreements.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure applies to third party agreements between the APBMT and the STCL and other entities whose services impact the cellular therapy product.

3.2 Designees from the APBMT Programs and STCL will be responsible for identifying the materials/services needed in order to function properly.

3.3 QSU will qualify vendors and ensure that they have the appropriate quality and compliance systems in place.

3.4 Duke Procurement will issue and maintain Purchase Orders (PO) for the selected vendor.

4 DEFINITIONS/ACRONYMS

4.1 APBMT: Adult & Pediatric Bone Marrow Transplant Program

4.2 PO: Purchase Order

4.3 QSU: Quality Systems Unit

4.4 Risk Grade: The grade assigned to a vendor based upon the impact to the APBMT/STCL programs should the vendor's service/material be interrupted or not meet appropriate quality standards.

4.5 STCL: Stem Cell Laboratory

4.6 Third Party Agreement: An agreement with the vendor for the purpose of supplying goods or services and adhering to standards that may affect the quality and safety of their service or goods.

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 The term "Third Party Agreement" is divided into two functions: one related to obtaining a PO, and the other related to qualifying a vendor.

8.2 Obtaining a PO

8.2.1 Once a vendor has been identified as meeting the needs of the APBMT Programs and STCL, the Duke University Procurement Department will determine if the PO needs to be renewed or if one needs to be submitted to the vendor.

8.2.2 Once the PO is approved, the APBMT and STCL facilities will then be able to place orders for the item(s) that is provided by the vendor.

8.2.3 PO agreements will only detail the deliverables, financial, and legal requirements of the vendor to Duke University.

8.2.4 Every time a PO is renewed, it will be reviewed to verify that the correct information is present in the PO.

8.3 Vendor Qualification

8.3.1 Vendors are not all qualified to the same standard; especially if their service/supply can be easily replaced or if there is minimal risk to cellular therapy products should they experience an unexpected quality event.

8.3.2 QSU will review the ability of the vendor to meet quality and compliance standards in accordance with *COMM-QA-002 Supplier Qualifications.*

8.3.3 Vendors will be re-reviewed according to the risk grade assigned to them per *COMM-QA-002 Supplier Qualifications*.

8.4 Written Agreement

8.4.1 A written agreement may be established with third parties whose services impact the quality and safety of the cellular therapy product or health and safety of the donor or recipient.

8.4.2 Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations and to comply with applicable laws and regulations and these standards.

8.4.2.1 Agreements should include the responsibility of the external parties to provide clinically relevant information related to products or services.

8.4.3 The APBMT Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the APBMT Program. If the APBMT program or an intermediary

facility receives cellular therapy products directly from a third-party provider, the program will attempt to obtain a written agreement with the following responsibilities defined:

8.4.3.1 Traceability and chain of custody of cellular therapy products.

8.4.3.2 Cellular therapy product storage and distribution.

8.4.3.3 Verification of cellular therapy product identity.

8.4.3.4 Review and verification of product specifications provided by the manufacturer, if applicable.

8.4.3.5 Readily available access to a summary of documents used to determine allogeneic donor eligibility.

8.4.3.6 Documented evidence of allogeneic donor eligibility screening and testing in accordance with applicable laws and regulations.

9 RELATED DOCUMENTS/FORMS

9.1 Duke University/Duke University Health System Outside Services Agreement

9.2 COMM-QA-002 Supplier Qualifications

9.3 COMM-QA-002 FRM1 Supplier Questionnaire FRM1

9.4 COMM-QA-002 FRM2 Supplier Impact Assessment FRM2

9.5 COMM-QA-002 JA1 Supplier Risk Assessment JA1

10 REFERENCES

10.1 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration.

10.2 FDA, CFR Title 21, Parts 200-299, 1270, 1271.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
04	B. Shen	Added Section 8.4.2.1 Agreement should include the responsibility of the external parties to provide clinically relevant information related to products or services.

Signature Manifest

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COMM-PAS-001 Third Party Agreement

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