



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Notifying Donors of Positive Infectious and Genetic Disease Test Results

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APBMT-COMM-010

NOTIFYING DONORS OF POSITIVE INFECTIOUS AND GENETIC DISEASE TEST RESULTS

1 PURPOSE

- 1.1 To provide guidance for notifying and counseling stem cell and other cellular therapy donors in event of positive infectious or genetic disease test results.

2 INTRODUCTION

- 2.1 Donor notification is a sensitive area as it relates to donor health, product safety, and prevention of possible disease transmission. This procedure outlines the steps taken to notify donors of positive test results.

3 SCOPE AND RESPONSIBILITIES

- 3.1 This procedure applies to all donors in the Adult and Pediatric Blood and Marrow Transplant (APBMT) Programs, including patient receiving cellular therapy. Physicians and Transplant Coordinators coordinating the care of these patients are responsible for ensuring the requirements of this procedure are successfully met.
- 3.2 The donor's care team, including the Attending Physician, Transplant Coordinator, and Advanced Practice Providers, will communicate with the donor or their parent(s) or legally authorized representative(s) if infectious disease or genetic testing results are positive.
- 3.3 The donor's physician is responsible for reporting communicable diseases to the appropriate regulatory authority when applicable.

4 DEFINITIONS/ACRONYMS

- 4.1 APBMT Adult and Pediatric Blood and Marrow Transplant

5 MATERIALS

- 5.1 Patient Education Material
- 5.2 Duke Medicine Infection Control Policy: Communicable Disease Reporting
- 5.3 Duke Medicine Clinical Laboratories Policy: Reporting Infectious Organisms and other Notifiable Test Results

6 EQUIPMENT

- 6.1 NA

7 SAFETY

- 7.1 NA

8 PROCEDURE

8.1 Guidelines for Notification and Counseling

- 8.1.1 The donor notification process should be initiated within seven working days from receipt of confirmed positive test results.
- 8.1.2 Compliance with Federal, state or local regulations is required.
- 8.1.3 Medically significant test results will be reported to the donor and, if the donor is a minor, their parents and/or legal guardian(s). See APBMT-COMM-001 *Donor Selection, Evaluation and Management* for more related processes.
- 8.1.4 Confirmed positive results:
 - 8.1.4.1 Upon receipt of results requiring notification and/or counseling:
 - 8.1.4.1.1 Notify the medical director and/or the attending physician.
 - 8.1.4.1.2 Notify the donor and/or their parents and/or legal guardian, as applicable, utilizing the most appropriate mode of notification.
 - 8.1.4.1.3 Distribute Fact Sheet results to the donor and/or their parents and/or legal guardian.
 - 8.1.4.2 Counseling will be provided in all cases where test results are positive. The donor and or their parent(s)/guardian(s) must be counseled in person for all confirmed positive HIV or Chagas disease test results. All other confirmed positive test results will be evaluated for medical significance and the need for formal counseling of the donor.
 - 8.1.4.3 If appropriate, the donor will be referred for medical intervention for the condition identified, if indicated.

8.2 State Notification

- 8.2.1 The donor's physician is responsible for reporting communicable disease per Duke University Hospital related policy: Communicable Disease Reporting.
- 8.2.2 The donor's physician is responsible for reporting communicable diseases to the North Carolina State Department of Health according to the time frame noted on the communicable disease reporting form.
- 8.2.3 The current list of reportable communicable diseases, reporting forms and instructions for completing are obtained at:
http://epi.publichealth.nc.gov/cd/lhds/manuals/cd/reportable_diseases.html

8.3 Counseling Guidelines

- 8.3.1 It is important to refer or counsel donors who have confirmed positive HIV or genetic disease testing results.
- 8.3.2 HIV positive donors will be referred to the Duke University Infectious Disease Clinic for confirmatory testing, counseling and treatment.
- 8.3.3 Donors testing positive for Chagas disease will be referred to an infectious disease specialist for further testing and treatment if required.
- 8.3.4 Donors testing positive for genetic diseases will be offered counseling through the Division of Genetics and Metabolism at Duke University.
- 8.3.5 In selected cases, in the pediatric program, the PBMT Attending Physician may choose to counsel the family rather than referring to a sub-specialty service.
- 8.3.6 For donors being counseled for confirmed positive infectious disease test results, inquire about previous blood donations within the last 5 years. Record where and when previous donations occurred to the best of the donor's recollection, on a separate authorization for release of test information form.
- 8.4 Donor Notification Records
 - 8.4.1 The Medical Director or donor's Attending Physician is responsible for maintenance of records associated with donor notification.
 - 8.4.2 These records will be maintained in the donor's medical record at Duke or their donor center.
- 8.5 Confidentiality
 - 8.5.1 Test results are considered confidential information and must be handled accordingly. Access to this information must be limited and disseminated only on a need-to-know basis.
 - 8.5.2 Employees who have access to donor names and related test results must follow HIPAA guidelines and sign a confidentiality statement. This confidentiality statement must be kept in the personnel files.

9 RELATED DOCUMENTS/FORMS

- 9.1 APBMT-COMM-001 Donor Selection, Evaluation and Management
- 9.2 Duke University Hospital related policy: Communicable Disease Reporting

10 REFERENCES

- 10.1 N/A

11 REVISION HISTORY

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05	Sally McCollum	Section 8.2 - added Duke University Hospital related policy: Communicable Disease Reporting Section 9- added Duke University Hospital related policy: Communicable Disease Reporting

Signature Manifest**Document Number:** APBMT-COMM-010**Revision:** 05**Title:** Notifying Donors of Positive Infectious and Genetic Disease Test Results**Effective Date:** 06 May 2021

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