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Utilization of a Donor Medical History Addendum

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COMM-QA-081
UTILIZATION OF A DONOR MEDICAL HISTORY ADDENDUM

1 PURPOSE

1.1 This procedure outlines the incorporation of an addendum, to supplement previously established donor screening tools in response to updates in Federal, State, or Local recommendations/guidelines.

2 INTRODUCTION

2.1 Obtaining a detailed medical history from consented donors, as applicable, donating for clinical use provides a method of screening for risk behaviors, inherited conditions and/or infectious diseases which could potentially be transmitted through transplantation of blood and/or tissue to a transplant recipient.

2.1.1 In the event the donor is a minor, processes outlined in this procedure, including obtaining a medical history, may involve the parent or legal guardian, as applicable, and in compliance with program specific policies.

2.1.2 In certain programs, the birth mother may function in the "donor" or the "donor" representative role in the donor screening process. The term "donor" will be used to comprehensively cover all such roles for the purposes of this document.

2.2 Standardized screening questionnaires, which are specific for each clinical and research program, have been developed to review the past and current medical history of the donor and his/her family. The medical history includes, but is not limited to, questions regarding past medical problems, medication use, travel history, as well as current and past lifestyle practices such as sexual history, risk behaviors, and illicit drug use.

2.3 As infectious disease risks may vary by geographical location and exposure risk may evolve over time, regulatory agencies may institute additional donor screening measures in response to such emerging infectious diseases and/or outbreaks, including the development of new donor screening recommendations.

2.3.1 Supplemental donor screening recommendations may require the development of an addendum to be used in conjunction with standardized routine screening tools.

2.3.2 Addendums may transition into permanent guidelines, or as risks subside, the additional screening measures may no longer be required.

2.4 The donor history addendum will be completed by one of the following, as applicable per program-specific procedures or guidelines:

2.4.1 Trained personnel during an interview with the donor after a signed informed consent has been obtained, if applicable.

2.4.2 The donor with oversight by trained personnel after a signed informed consent has been obtained, if applicable.

2.5 The donor history addendum shall be administered/obtained and documented while the donor, or person completing the form is able to concentrate on the information, is not distracted, and is not under the influence of sedation, mind-altering medications or pain.

2.6 The donor history addendum shall be administered/obtained in a language the donor and/or mother understands. If an interpreter or translator is utilized, the identity of the interpreter or translator shall be documented or as outline in program-specific policy or guidelines. Family members shall not serve as interpreters or translators.

2.7 In the research setting, compliance with study-related policy and procedure will be adhered to at all times.

3 SCOPE AND RESPONSIBILITIES

3.1 All program staff involved in the donor screening process are responsible for ensuring the requirements of this procedure are successfully met.

3.2 This procedure describes the requirements for administering a donor history addendum to consented donors and/or mothers, as applicable, in the specific program – Carolinas Cord Blood Bank (CCBB), Adult and Pediatric Blood and Marrow Transplant Programs (APBMT), Thymus Transplant Program, and the Marcus Center for Cellular Cures (MC3).

4 DEFINITIONS/ACRONYMS

4.1 APBMT Adult and Pediatric Blood and Marrow Transplant Programs

4.2 CCBB Carolinas Cord Blood Bank

4.3 MC3 Marcus Center for Cellular Cures

5 MATERIALS

5.1 Informed Consent document, if applicable

5.2 Identification Labels

5.3 Ink pen (black ballpoint preferred, blue acceptable)

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Program Leadership will evaluate temporal changes to Federal, State, or local mandates or guidelines outlining donor screening processes.

8.1.1 Potential impact and applicability of revised recommendations will be determined for each program.

8.1.2 When warranted, a donor medical history addendum will be created to supplement standardized donor screening tools already in use.

8.1.3 Communication outlining the addendum, scope, and implementation plans will be distributed to applicable program leadership.

8.1.4 Once an addendum is deemed no longer required, the associated form (FRM) will be archived in MasterControl and communication outlining cessation of use will be distributed to applicable program leadership.

8.2 Steps for administration of any donor medical history addendum should comply with program-specific policies for donor screening. At a minimum:

8.2.1 Prior to administration of the donor medical history addendum, verify the following:

8.2.1.1 The donor has completed all consenting steps as required in program-specific policies and procedures.

8.2.1.2 The donor has completed any program-specific standardized health history questionnaire(s), as applicable.

8.2.2 At initiation of the medical history addendum interview/administration process, ensure that:

8.2.2.1 Processes are conducted with discretion and with privacy in mind for the donor.

8.2.2.2 If a donor medical history addendum will be self-administered, the interviewer will review and verify the answers with the individual who has filled out the questionnaire form, if required per program-specific policies and/or guidelines.

8.2.3 Additional clarification or approval may be required.

8.2.3.1 Responses to some questions may require further clarification from the donor.

8.2.3.2 Responses may require approval from the Medical Director or designee before being approved to donate. Directions for Medical Director approval can be found on each individual addendum form.

8.2.3.3 Program-specific policies for donor inclusion/exclusion determination and documentation will be followed.

8.3 Documentation and labeling

8.3.1 Documentation will be completed in compliance with program-specific polices.

8.3.2 After questions have been reviewed and answers clarified, the program staff member will ensure that all forms are fully and accurately completed:

8.3.2.1 If applicable, confirm that all signatures have been obtained and dates designated appropriately.

8.3.3 Label each page of the donor medical history addendum with appropriate Identification labels or as outlined in program-specific procedures.

8.4 Document storage

8.4.1 The donor medical history addendum should be stored with program-specific donor history questionnaires, per the associated program-specific records management procedures.

9 RELATED DOCUMENTS/FORMS

9.1 `COMM-QA-081 FRM1 Donor Risk Questionnaire Addendum – Coronavirus

9.2 COMM-QA-081 FRM2 Donor Risk Questionnaire Addendum – Coronavirus (Spanish)

9.3 COMM-QA-081 FRM3 Donor Risk Questionnaire Addendum – MonkeyPox

9.4 COMM-QA-081 FRM4 Donor Risk Questionnaire Addendum – MonkeyPox (Spanish)

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	Sally McCollum	Section 9: Addition of two forms: COMM-QA-081 FRM3 Donor Risk Questionnaire Addendum – MonkeyPox; COMM-QA-081 FRM4 Donor Risk Questionnaire Addendum – MonkeyPox- Spanish.

Signature Manifest

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