American Association of Tissue Banks®

Guidance Document

Physical Examination Birth Mothers

[No. 1, December 15, 2023]

Certain American Association of Tissue Banks (AATB) guidance documents describe mandatory requirements with which accredited tissue banks must comply fully, whereas other AATB guidance documents present only recommendations regarding possible approaches, but not necessarily the only approach, for compliance by accredited tissue banks with AATB Standards. ***This guidance document is advisory in nature only and does not establish legally enforceable responsibilities with which AATB accredited tissue banks must comply.*** *Absent imposition of a specific requirement by AATB that a tissue bank must comply with one or more of the provisions of this guidance document, its provisions (1) should be viewed only as recommendations reflecting AATB's current thinking on the subject, unless specific AATB Standards or regulatory or statutory requirements are cited, (2) the use of the word "should" means that something is suggested or recommended, but not required, and (3) the recommendations do not represent the sole approach, and alternative approaches may be satisfactory to establish compliance with Standards. This guidance document is intended solely for the use of AATB accredited tissue banks in conjunction with the AATB's Standards for Tissue Banking.*

American Association of Tissue Banks
8200 Greensboro Drive
Suite 404
McLean, Virginia 22102
(703) 827-9582 aatb@aatb.org

Additional copies of this Guidance Document are available on the AATB website www.aatb.org. In addition, comments on this document may be submitted at any time to the AATB. The Association will review any comments received and revise the Guidance Document as appropriate. All requests and comments should be addressed to:

American Association of Tissue Banks
8200 Greensboro Drive
Suite 404
McLean, Virginia 22102
www.aatb.org

For questions on the content of the document, please contact AATB at: standards@aatb.org.

Mention of specific products or equipment in this AATB publication does not represent an endorsement of such products or equipment by the AATB, nor does it necessarily indicate a preference for those products or equipment over other similar competitive products or equipment.

This guidance document is advisory in nature only. Absent imposition of a specific requirement by AATB that a tissue bank comply with some or all of the provisions of this guidance document, the provisions of this document, including forms and/or procedures presented as examples, do not establish legally enforceable requirements and do not constitute an endorsement by AATB of these recommendations as the only acceptable practice for compliance with the *Standards for Tissue Banking (Standards)*. The publication of this guidance document does not constitute an endorsement by the AATB of these recommendations as the only acceptable practices. In addition, the AATB does not imply or guarantee that the materials meet federal, state, or other applicable requirements. It is incumbent on the reader who intends to use any information, forms, policies, or procedures contained in this publication to evaluate such materials for use in light of particular circumstances associated with his or her facility.

Efforts are made to have publications of the AATB consistent regarding acceptable practices. However, for several reasons, they may not be. As new developments in the practice of tissue banking occur, changes may be recommended to the *Standards.* It is not possible, however, to revise each publication at the time such a change is adopted. Thus, it is essential that the most recent edition of the *Standards* be consulted as a reference regarding current acceptable practices. The AATB expressly disclaims any liability arising from any inaccuracy or misstatement herein.

The AATB recognizes the efforts of the following individuals who generously donated their time and expertise to creating this document:

Authors

Bill Cassarly
Rhonda Heston
Holly Hewitt
Anna McDonald
Anna Tirrell

Contributors

Patrick AbdelMessih
Darcy Beckler
Faith Case
Nancy Dock
Bridget Gipper
Matthew Kuehnert
Jami Otis
Uzair Rajput
Katherine Sweetin
Hannis Thompson
Kurt Weber

AATB Liaisons

Beverly Bliss
Melissa Greenwald
Kip Hanks

TABLE OF CONTENTS

I. INTRODUCTION

A. History and Purpose

Throughout the birth tissue donation industry, different processes have been established to satisfy the requirement of having a current physical examination documented as part of donor-eligibility determination.

The purpose of a physical examination of a living donor is to assess for physical signs of a relevant communicable disease and for signs of any risk factor for such a disease.

This Guidance Document provides direction on the various ways a physical examination can be obtained for birth mothers that satisfies regulatory requirements, as physical exam findings relevant to tissue donation may include different factors than what may be clinically relevant to providers evaluating women for delivery found on an admission H&P. This document assists with understanding of standard prenatal care and the documents that are typically generated during prenatal course and delivery. While both AATB and FDA require documentation and evaluation of the health and physical status of the newborn as part of the donor-eligibility determination, that is outside the scope of this document.

These options are discussed and outlined in this document, along with examples of forms that may be used to satisfy the physical examination requirement for the birth mother. It is up to each individual bank's medical director to determine exactly which condition or finding would be a contraindication to donation. The forms contained in this document provide examples that can be used by banks to develop their own robust forms and procedures.

Refer to AATB Standards:

D3.000 Informed Consent
D4.100 Donor Screening
D4.130 Physical Examination
D4.140 Donor Risk Assessment Interview (DRAI)
D4.141 Family History and Genetic Background
D4.150 Relevant Medical Records Review
D4.230 Required Infectious Disease Tests
D5.720 Delivery and Post-Delivery Records
F1.110 Records for Review
F1.120 Infectious Disease Risk Review
Appendix II: Criteria for Preventing Transmission of RCDADs Through Transplantation of Human Tissue

B. Definitions and Acronyms

Acquisition: The point after delivery at which tissue is under the control of the tissue bank.

Attestation: A written declaration that formally certifies that something exists or is the case.

Birth Tissue (BT): Gestational tissue donated at the time of delivery of a living newborn. This includes placenta, chorionic membrane, amniotic membrane, placental/chorionic disc, umbilical veins, and umbilical cord tissue. While Wharton's jelly and amniotic fluid are generally considered to fall in the category of birth tissue, FDA has stated that amniotic fluid is not, by definition as found within 21 CFR 1271.3, an HCT/P. Wharton's jelly is considered a "351 HCT/P" by the FDA, as most uses of this tissue are for non-homologous, and it's more than minimally manipulated.

Designee: A medical professional as an alternate signer (RN, LPN, DO), who is involved in patient care and is qualified to perform physical examinations and review records, and due to those qualifications may sign an attestation regarding the birth mother's physical examination/general health.

Directed Physical Examination: An examination of only parts of the body that are necessary to further evaluate for Relevant Communicable Disease Agents or Diseases based upon relevant medical history and review of available records.

HIPAA: Health Insurance Portability and Accountability Act. Mandates industry-wide standards for health care information and requires the protection and confidential handling of protected health information.

Physical Examination Checklist: A specified listing of the established elements of a birth mother's physical examination.

Physical Examination of a Birth Mother: A documented evaluation of a birth mother's body to determine whether there is evidence associated with Relevant Communicable Disease Agents or Diseases and to determine the overall health of the birth mother.

Physician: A licensed medical doctor (MD) or doctor of osteopathy (DO) involved in the birth mother's care, either during her prenatal course or during admission for delivery.

RCDAD(s): Relevant Communicable Disease Agents or Diseases. A potentially infectious disease agent that may pose a risk of transmission to recipients of, or those who come in contact with, tissues. These disease agents/diseases: have sufficient incidence and/or prevalence to affect the potential donor population or may be accidentally or intentionally released in a manner to place potential donors at risk for infection; could be fatal, life-threatening, result in permanent impairment, or necessitate medical or surgical intervention to preclude permanent impairment; and, for which appropriate screening measures have been developed or an appropriate screening test for donor specimens has been FDA-licensed, cleared, or approved, and is available.

RCDADs applicable to **all tissue donations** include the following:

- Human immunodeficiency virus (HIV), types 1 and 2
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human transmissible spongiform encephalopathy (TSE); including Variant Creutzfeldt-Jakob disease (CJD)
- *Treponema pallidum* (syphilis)
- Sepsis
- West Nile virus
- Zika virus infection
- Vaccinia (virus used in Smallpox vaccine)

Other testing/screening performed on BT donors either for purpose of donation or during prenatal course include:

- Human T-lymphotropic virus (HTLV), types I and II (otherwise required for donors of leukocyte-rich cells and tissue)
- *Chlamydia trachomatis* (CT) (otherwise required for donors of reproductive tissue)
- *Neisseria gonorrhea* (NG) (otherwise required for donors of reproductive tissue)

The following is a list of additional communicable disease agents and diseases that may be transmissible by HCT/Ps. Refer to current FDA Guidance and AATB Standards for requirements or updates on current RCDADs.

- Rabies
- Ebola virus disease
- Encephalopathies
- *Mycobacterium tuberculosis*
- Hansen's disease (leprosy)
- Systemic mycosis

Relevant Medical Records: A collection of documents including, but not limited to, a current donor risk assessment interview, physical examination or attestation of examination, laboratory test results performed during prenatal course, laboratory test results at time of delivery as is required for tissue donation, as well as information obtained from any source or records which may pertain to donor eligibility regarding high-risk behaviors, clinical signs and symptoms for any RCDAD, and/or treatments related to medical conditions suggestive of such risk.

Tissue Bank: An entity that provides or engages in one or more services involving tissue from living or deceased persons for transplantation purposes. These services include obtaining authorization and/or informed consent, assessing donor eligibility, recovery, collection, acquisition, processing, storage, labeling, distribution and dispensing of tissue.

Vertical Transmission: An infection caused by pathogens (including bacteria and viruses) that can be transmitted from the mother to an embryo, fetus, or baby during pregnancy or childbirth.

Acronyms List:

- ACOG: American College of Obstetricians and Gynecologists
- ASA: American Society of Anesthesiologists
- CT: *Chlamydia trachomatis*
- GBS: Group B streptococcus
- H&P: History and physical examination
- HPV: Human papilloma virus
- APGAR: Activity/muscle tone, Pulse/heart rate, Grimace, Appearance, Respiration/breathing
- CBC: complete blood count
- NG: *Neisseria gonorrhea*
- OB: Obstetrics
- PAP: Pap smear, also called Pap test and Papanicolaou test
- ROS: Review of Systems
- SOPM: Standard Operating Procedure Manual

II. BACKGROUND

A. Documentation generated during typical prenatal care:

This section provides information on typical prenatal care provided to pregnant women. While documentation of this care varies with each OB practice, this section is meant to provide information as to what records are typically generated by OB providers.

While it is recommended that the tissue bank obtain all these prenatal records, the tissue bank should establish which records are required. In the case where a pregnant woman may not have established care at the beginning of her pregnancy, the tissue bank should also establish an acceptable length of time of prenatal care in their SOPs.

This table lists out the normal visits to OB care provider:

Between weeks 1-32:	Between weeks 32-37:	At 36+ weeks:
Routine OB visit once a month	*Routine OB visit every 2 weeks*	*Routine weekly OB visits, with cervical exam each time*
The first OB visit typically confirms **family history, standard prenatal labs** (HIV, HBV, syphilis and screening for NG/CT) are taken at this time. **Full physical examination** **PAP** if indicated, (based on the medical judgement	At 35/36 weeks: **r/v Group B Strep (GBS) swab.** Repeat **NG/CT**, **syphilis, HIV**	**NG and CT** screening if the patient has no risk factors. CDC guidelines state NG/CT screen performed when the woman is <25yo, or ≥25yo WITH risk factors. ACOG recommendations: All pregnant women should be screened for NC/CT and syphilis if the woman is

of the attending OB physician or their preferred general practice). **Genetic screening** – if indicated and if birth mother consents to testing.		<25yo, or ≥ 25yo WITH risk factors.

In conjunction with these visits, pregnant women are screened and/or tested for vertically transmitted diseases by their OB providers. The acronyms commonly seen in OB records are TORCH or CHEAPTORCHES, for those bacteria, viruses, and other organisms that could be passed from mother to child. During patient visits, these diseases are discussed with the patient to determine if there is an exposure risk, and testing may be performed. No further action is generally taken when test results are negative; if test results are positive, treatment is prescribed, if available. These acronyms are discussed in the table below:

		Screened, Tested, or Treated:
T	**T**oxoplasmosis	Screened for exposure risk at new OB visit and advised how to avoid exposure. Example, told not to change cat litter.
O	**O**ther infections: Parvovirus, Coxsackievirus, Chickenpox, CT, NG, HIV, Lyme Disease, Syphilis, Zika	CT, NG, HIV, Syphilis – testing performed. Zika: travel history discussed. Lyme Disease – only tested if exposure concern.
R	**R**ubella	Tested to show immunity at new OB visit. Vaccination offered post-partum.
C	**C**ytomegalovirus	Only tested if exposure concern. Example, working with small children, symptoms such as rash or viral illness, or abnormal prenatal ultrasound results which may prompt further work-up.
H	**H**erpes simplex virus	Screened with patient if infection history. Some OB offices test for seropositivity. Suppressant prescribed at week 36 if needed.

		Screened, Tested, or Treated:
C	**C**hickenpox and shingles	Infection history discussed and Varicella titers drawn at new OB visit. Vaccination offered post-partum.
H	**H**epatitis, B and C	Hepatitis B and C tested.
E	**E**nteroviruses	Patients are rarely ever tested, and only worked up if symptoms of nausea/vomiting persist.

A	**A**IDS (HIV infection)	Tested.
P	**P**arvovirus B19	Abnormal prenatal ultrasound results which may prompt further work-up.
T	**T**oxoplasmosis	Screened for exposure risk at new OB visit and advised how to avoid exposure. Example, told not to change cat litter.
O	**O**ther Infections (Group B Streptococcus, Listeria, Candida, Lyme disease)	Group B strep tested at ~ 36 weeks. Candida treated if symptoms. Lyme disease tested if exposure and/or symptoms. *Listeria* – patients advised to avoid exposure.
R	**R**ubella	Tested to show immunity at new OB visit. Vaccination offered post-partum.
C	**C**ytomegalovirus	Only tested if exposure concern. Example, working with small children, or has symptoms such as rash or viral illness, or abnormal prenatal ultrasound results which may prompt further work-up.
H	**H**erpes simplex virus	Screened with patient and suppression medication prescribed – this varies by OB provider if patient is sero positive only and never had an outbreak.
E	**E**verything else sexually transmitted (gonorrhea, *Chlamydia* infection, *Ureaplasma urealyticum*, human papillomavirus)	NG and CT tested during OB visits. Genital tract infections are treated if patient is showing symptoms. HPV is screened via a PAP smear. Condylomas can be removed as necessary, or often treated postpartum.
S	**S**yphilis	Testing performed.

B. Records from Hospital Admission

Once a woman is admitted to hospital to deliver, the following records are typically generated:

H&P: H&P exam performed or attested to within 24-hours of admission. Included in this document is a standard physical examination of a woman upon admittance to the hospital who is preparing to give birth. This H&P exam includes a standard ROS and a review or evaluation of general anatomy. This ROS and anatomical review may cover:

Vitals
Constitutional symptoms
Eyes, Ears, Mouth, Nose, Throat
Cardiovascular
Respiratory
Gastrointestinal
Genitourinary
Musculoskeletal

Integumentary
Neurological
Psychiatric
Endocrine
Hematologic/lymphatic
Allergic/immunologic

Anesthesia evaluation: If a c-section is performed, or an epidural or spinal anesthesia are provided for a vaginal birth, the birth mother will be seen by an anesthesiologist. The anesthesiologist typical confirms information on the H&P, and the anesthesiology evaluation would include any updated information obtained, along with the physical evaluation performed by the anesthesiologist.

The ASA classification (below table) used by anesthesiologists provides information relevant to the health of the woman:

ASA I	A normal healthy patient: Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with a mild systemic disease - Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease.
ASA III	A patient with a severe systemic disease - Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, a moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life - Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis

If used, this ASA classification can be found within the anesthesia evaluation records.

Delivery Record: Documents date and time of delivery, initial evaluation including information on health status of the newborn, documented APGAR score, and other information such as amniotic fluid characteristics.

Dictated Operative Report: This document is dictated and signed by the physician and includes both pre-op and post-op diagnosis and any intra-operative events.

Lab Results: Blood is drawn on admission to hospital for CBC – which may include further HIV and syphilis testing.

The Tissue Bank shall establish minimum requirements for obtaining available hospital generated relevant medical records (J1.200).

III. Options for Tissue Banks to Document a Physical Examination of a Birth Mother

This section addresses three acceptable options to obtain a robust physical examination of a birth mother. Whichever approach is used to document a physical examination, this does not absolve the tissue bank of obtaining all relevant records. It should be noted that AATB and FDA require evaluation of the health and physical status of the newborn, but that is outside the scope of this document.

A. Physical Examination Performed for the Purpose of Donation

This option addresses the performance and documentation of a physical examination specifically for the purpose of donation. regardless as to whether there is already a physical examination performed for birth event.

Tissue banks should develop SOPs that cover:

- Language in the informed consent record, regarding the individual's consent for this physical examination specifically performed for the purpose of donation and is not part of her prenatal care or any examination performed during admission.

- How to disseminate any physical examination findings, including any required notification to donor's treating medical personnel, if the examination was performed by an auxiliary medical professional not directly involved in the individual's care.

    - Providers should be made aware that there may be other documentation regarding an individual's general health generated through tissue donation process.

    - Language should be included in contracts with providers and/or hospitals that addresses who completes physical examination for the purpose of donation.

    - Documented training for those medical personnel performing this physical examination for the purpose of donation.

An example form documenting physical examination performed for the purpose of donation is below. (**Tissue banks may also develop their own form**.)

PHYSICAL EXAMINATION of BIRTH MOTHER	
Vital Signs within normal limits: • Body temperature • Pulse rate • Respiration rate • Blood pressure	☐ Yes ☐ No
Constitutional Healthy appearing	☐ Yes ☐ No
Eyes – conjunctiva normal, sclera white	☐ Yes ☐ No
Neck – no lymphadenopathy present	☐ Yes ☐ No
Breasts – no skin changes, no discharge, no masses on palpation	☐ Yes ☐ No
Gastrointestinal Abdominal Examination – non-tender to palpation, normal bowel sounds, no masses Liver and Spleen – no hepatomegaly present, non-tender to palpation Hernias – no hernias present	☐ Yes ☐ No
Genitourinary External Genitalia – normal appearance, no unusual discharge Vagina – no unusual discharge, no masses Bladder – non tender to palpation Urethra – structural support normal Cervix – non-tender to palpation Uterus – non-tender to palpation, no masses present Perineum – no lesions present Anus – no lesions, no masses	☐ Yes ☐ No
Lymphatic – No lymphadenopathy present	☐ Yes ☐ No
Skin – No rashes, no lesions, no areas of discoloration, no unexplained jaundice	☐ Yes ☐ No
Are there any other physical evidence/signs of a current infection, or an unexplained rash/ petechiae, fever, skin lesions, swollen lymph nodes, or others symptoms of a virus?	☐ Yes ☐ No
Are there physical evidence/signs of any sexually transmitted diseases (rash genital ulcers, herpes simplex, chancroid genital lesions, etc.) or syphilis?	☐ Yes ☐ No
Is there evidence of needle tracks or other non-medical injection site?	☐ Yes ☐ No
Findings and Other Comments:	
Performed by (signature and printed name): Date:	
Title: □ MD/DO □ CNM □ RN/LPN □ Other _____	

B. Attestation of Physical Examination

This option outlines the performance of an attestation, where a physical examination has already been performed, and a member of the birth mother's obstetrical care team reviews and signs a form confirming absence of any physical examination findings that would be a contraindication to donation.

Tissue banks shall develop SOPs related to attestation of a physical examination (J1.200) which address at a minimum:

- Information to be reviewed with or by the physician, or designee, as part of examination attestation. (See following form)

- Process of completing the attestation, which may also be obtained by the responsible tissue bank representative when interviewing the physician or designee, rather than signed by the physician or designee themselves.

- Whether the physician/medical provider performing the exam or the responsible tissue bank representative signs an attestation, the signature(s) attest that there are no physical examination findings that would be a contraindication to donation, as listed in the attestation form.

- Obtaining all available relevant records listed in section II, along with the birth mother's prenatal records, to support the attestation.

An example form of documented attestation with the physician or healthcare provider is below. (**Tissue banks may also develop their own form**):

PHYSICAL EXAMINATION ATTESTATION

Hospital Physical Exam Performed? Date: _____

Review the questions below with a qualified medical staff member associated with the delivery.

Name of Medical Professional that provided answers: _____

Title: □ MD/DO □ CNM □ RN/LPN □ Other _____

1. Is there physical evidence of any sexually transmitted diseases (including genital rash/outbreak, ulcers, vesicles, chancre, condyloma, condyloma lata, or rashes on palms or soles)?	☐ Yes ☐ No
2. Is there physical evidence/signs of a current infection, or an unexplained rash/ petechiae, fever, skin lesions, swollen lymph nodes, or other signs of a virus?	☐ Yes ☐ No
3. Is there physical evidence of non-medical percutaneous drug use such as needle tracks.	☐ Yes ☐ No
4. Has an examination evaluated for absence of signs of non-medical percutaneous drug use, including examination of tattoos that may cover needle tracks?	☐ Yes ☐ No
5. Are there any abnormal ocular findings consistent with vaccinal keratitis?	☐ Yes ☐ No
6. Are there any scabs consistent with recent smallpox vaccinations, Eczema vaccinatum, or necrotic lesions consistent with vaccinia necrosum?	☐ Yes ☐ No
7. Unexplained jaundice, enlarged liver (hepatomegaly) or icterus?	☐ Yes ☐ No
8. Is there any other physical evidence of any infectious diseases, or a current systemic infectious illness? (If yes, state information obtained)	☐ Yes ☐ No

COMMENTS/FINDINGS:

Interview for completion of attestation performed by (signature):

Print name:

Date:

C. Review of Relevant Medical Records Identifying Documented Physical Examinations by Medical Professionals Involved in the Birth Mother's Care

Review of relevant medical records identifying documented physical examinations by medical professionals involved in the birth mother's care.

This section discusses obtaining all relevant records generated from the beginning of a birth mother's prenatal care, through those records generated during admission to deliver:

- Within their SOPMs, tissue banks shall establish and define the records needed to enable a complete review (J1.200). See section II (Background) above for an overview of typically available documentation.

- The review of these records should contain all the information needed to meet the physical examination requirement as defined by the tissue bank's medical director.

- If the records do not contain the required information (for example, negative test of cure documentation post treatment of infection), then SOPMs should include this as an instance when a directed physical exam must be performed.

- In the event the birth mother has not had continuous care, or has established care later in pregnancy, the tissue bank should establish an acceptable length of time for prenatal care, to ensure robust documentation.

Provided below is an example list of information that should be reviewed to ensure a birth mother is free of infections, and infectious diseases. It is not an all-inclusive list, as this list should be developed and approved by the tissue banks medical director. Some information may vary by state depending on where finished allografts are distributed.

INFORMATION REVIEWED for PHYSICAL EXAMINATION		
Physical Exam Date:		
Prenatal and Perinatal Records Reviewed for:	**Present**	**Notes**
1. Medical provider or hospital-generated records, including those containing review of systems		
2. Current Admission/Delivery H&P Examination		
3. Intraoperative records		
4. Confirmation of no current or active disease or systemic infection		
5. Additional records obtained based on information provided by the birth mother (provide a list)		
Comments / Findings:		
Based on this review, there is sufficient documented information to determine that the requirements for a physical exam are: ☐ COMPLETED or ☐ NOT COMPLETED for further donor-eligibility determination review. ☐ MORE INFORMATION REQUIRED (LIST DOCUMENTATION REQUESTED):		
_____ Medical Director _____ Date		

D. Directed Physical Examination: Follow up of Discordant Information

Occasionally, information is obtained or otherwise discovered that contains discordant information about a body part/system, found to be unavailable in existing records. Such circumstances may warrant a limited, directed physical examination to resolve any discrepancies or missing data.

SOPs should establish why, and under what circumstances directed physical exams are performed and documented. The additional information from a directed physical exam must be performed by a responsible and trained person and the information must be verifiable, either via a directed physical examination or obtaining records post infection, which confirms any treatment has been successful.

A directed physical examination should encompass a further examination of the body part or region in question. Instances where a directed physical exam should be performed may include:

- Any history or information about the birth mother, obtained from the completed donor risk assessment interview, is determined to be discordant with other relevant records.

- Any of the established requirements for information needed within the physical examination or medical record is lacking or inconclusive.

- If the birth mother's H&P examination is not performed or available at the time of delivery or is incomplete based on the pre-established requirements.

Following is an example of a form that may be used to document a directed physical examination. Another example of documenting a directed physical examination can be found in Appendix III Tissue Donor Physical Assessment Form Requirements.

Directed Physical Examination of Birth Mother

(Mark only portions of the Physical Examination performed, otherwise select NP)

Please indicate the reason / issue being addressed by the directed physical examination:	WNL (yes or no) OR not performed (NP)
Vital Signs: • Body temperature • Pulse rate • Respiration rate • Blood pressure	☐ Yes ☐ No ☐ NP
Constitutional Healthy appearing	☐ Yes ☐ No
Eyes – conjunctiva normal, sclera white	☐ Yes ☐ No
Neck – no lymphadenopathy present	☐ Yes ☐ No
Breasts – no skin changes, no discharge, no masses on palpation	☐ Yes ☐ No
Gastrointestinal Abdominal Examination – non-tender to palpation, normal bowel sounds, no masses Liver and Spleen – no hepatomegaly present, non-tender to palpation Hernias – no hernias present	☐ Yes ☐ No
Genitourinary External Genitalia – normal appearance, no unusual discharge Vagina – no unusual discharge or masses Bladder – non-tender to palpation Urethra – structural support normal Cervix – non-tender to palpation Uterus – non-tender to palpation, no masses present Perineum – no lesions present Anus – no lesions, no masses	☐ Yes ☐ No
Lymphatic – No lymphadenopathy present	☐ Yes ☐ No
Skin – No rashes, no lesions, no areas of discoloration	☐ Yes ☐ No
1. Is there physical evidence of any sexually transmitted diseases (Including genital rash/outbreak, ulcers, vesicles, chancre, condyloma, condyloma lata; or rashes on palms or soles)?	☐ Yes ☐ No
2. Is there physical evidence/signs of a current infection, or an unexplained rash/ petechiae, fever, skin lesions, swollen lymph nodes, or others signs of a virus?	☐ Yes ☐ No
3. Is there evidence of needle tracks or other non-medical injection site?	☐ Yes ☐ No

Findings or other comments:	**Printed name:**	**Signature/Date:**

III. References

1. Current AATB Standards for Tissue Banking, McLean, VA

2. FDA Code of Federal Regulations Title 21, Part 1271

3. FDA: Eligibility Determination for Donors of HCT/Ps, Guidance for Industry, August 2007