CORRELATIVE SCIENCE PROCEDURE MANUAL

AFT-16: PHASE II TRIAL OF INDUCTION IMMUNOTHERAPY WITH ATEZOLIZUMAB FOR PATIENTS WITH UNRESECTABLE STAGE IIIA AND IIIB NSCLC ELIGIBLE FOR CHEMORADIOTHERAPY WITH CURATIVE INTENT

VERSION: 3.0

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AFT-16 Correlative Science Procedure Manual Signature Page

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Prepared by:

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1. PURPOSE

This document describes the procedures required for the collection, shipping, and processing of biospecimens from all patients enrolled or registered on AFT-16. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the AFT Biorepository (AFB) (i.e., Siteman Cancer Center Tissue Procurement Core at Washington University), Ohio State University (OSU), and HistoGeneX (HGX) prior to their use for protocol-specified and future, unspecified correlative science research studies. This document should be used by staff involved with any aspect of the AFT-16 study biospecimen collection, processing, and submission, including staff at satellite institutions.

2. SCOPE

This document applies to all biospecimens collected specifically for the AFT-16 study only. Please refer to the study protocol-specific language for additional details regarding eligibility, participant enrollment, data submission, and specific procurement procedures. Please ensure that you are reading the most updated version of this document. This document may experience minor updates, revisions, and clarifications independent of a formal protocol amendment. The most recent version of this document can be found on the AFT BioMS web site which is accessible via the AFT portal: (https://alliancefoundationtrials.org)

3. CONTACT INFORMATION

3.1. Please send any questions and problems related to protocol administration, eligibility, patient registration, and data submission, to the AFT Project Manager at: AFT16@alliancefoundationtrials.org or 1-617-525-8347.

3.2. For specific questions about kits or shipments, please contact the Siteman Cancer Center Tissue Procurement Core at: 1-314-454-7615 or tbank@wudosis.wustl.edu.

3.3. For questions about using the AFT BioMS web application for ordering kits, or registering and shipping biospecimens, please contact: 1-855-642-4667 or aftbiomshelp@email.wustl.edu

3.4. For any other questions about biospecimen procurement and shipping procedures, please contact the AFB Program Manager at: 1-314-747-4402 or afbhelp@email.wustl.edu

4. SITE PREPARATION

4.1. Please refer to the AFT-16 protocol for any specific requirements related to patient enrollment, registration, and regulatory compliance.

4.2. The AFT BioMS application is used for both requesting biospecimen collection kits and for logging the collection and shipment of biospecimens to the AFT Biorepository, Ohio State University, or HistoGeneX. For training and assistance in using the AFT BioMS application, please see the AFT BioMS web site which is accessible via the AFT portal: https://alliancefoundationtrials.org or contact the AFT BioMS Help desk at: aftbiomshelp@email.wustl.edu or 1-855-642-4667.

4.3. Prior to collection of biospecimens, a biospecimen collection kit must be at the collection site. Please see section 6 for requesting biospecimen collection kits. Please allow at least 10 working days to receive the collection kit.

4.4. Please confirm that your institutional pathology department will release a tumor tissue paraffin block or will be willing to submit tissue section slides from such a block, at each required time point designated in this document and in the study protocol. An institution whose pathology department is unwilling to comply with tumor block or slide submission should not enroll patients to this study.

5. COLLECTION SCHEMA

The following biospecimens are to be collected at each of the time points specified below. Please refer to individual collection kit instructions, biospecimen collection and processing methods, and specific shipping procedures below

Time Point	Biospecimen	Quantity	Collection / Processing Method	Recipient Lab	Notes
Screen	Unstained tumor tissue slides	4	Fixed tissue slides (8.3)	HistoGeneX (10.2)	1
Screen	Fixed tumor tissue block	1	Fixed tissue blocks (8.2)	AFB (10.4)	2
Screen	Unstained tumor tissue slides	20	Fixed tissue slides (8.3)	AFB (10.4)	2
Screen	Fixed tumor tissue block (primary DX)	1	Fixed tissue blocks (8.2)	AFB (10.4)	3
Screen	H/E stained tumor tissue slide (primary DX)	1	Tissue sections (8.4)	AFB (10.4)	3
Screen	8 micron tissue sections (primary DX)	10	Tissue sections (8.4)	AFB (10.4)	3
Screen	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
Screen	Whole blood (ACD tube)	2 x 5 ml	Whole blood- ACD tube (9.2)	OSU (10.3)	5
Screen	Whole blood (Heparin tube)	2 x 10 ml	Whole blood- Heparin tube (9.3)	OSU (10.3)	5
Day 1-Concurrent	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
Day 1-Concurrent	Whole blood (ACD tube)	2 x 5 ml	Whole blood- ACD tube (9.2)	OSU (10.3)	5
Day 1-Concurrent	Whole blood (Heparin tube)	2 x 10 ml	Whole blood- Heparin tube (9.3)	OSU (10.3)	5

C1D1-consolidation	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
C1D1-consolidation	Whole blood (ACD tube)	2 x 5 ml	Whole blood- ACD tube (9.2)	OSU (10.3)	5
C1D1-consolidation	Whole blood (Heparin tube)	2 x 10 ml	Whole blood- Heparin tube (9.3)	OSU (10.3)	5
3 mo. post Rx	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
3 mo. post Rx	Whole blood (ACD tube)	2 x 5 ml	Whole blood- ACD tube (9.2)	OSU (10.3)	5
3 mo. post Rx	Whole blood (Heparin tube)	2 x 10 ml	Whole blood- Heparin tube (9.3)	OSU (10.3)	5
6 mo. post Rx	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
6 mo. Post Rx	Whole blood (ACD tube)	2 x 5 ml	Whole blood- ACD tube (9.2)	OSU (10.3)	5
6 mo. post Rx	Whole blood (Heparin tube)	2 x 10 ml	Whole blood- Heparin tube (9.3)	OSU (10.3)	5
End of treatment	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
End of treatment	Whole blood (ACD tube)	2 x 5 ml	Whole blood- ACD tube (9.2)	OSU (10.3)	5
End of treatment	Whole blood (Heparin tube)	2 x 10 ml	Whole blood- Heparin tube (9.3)	OSU (10.3)	5
3 months after end of treatment	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4
6 months after end of treatment	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4

12 months after end of treatment	Whole blood (BCT tube)	2 x 8 ml	Plasma for cfDNA (9.1)	AFB (10.4)	4

NOTES:

1. Cut 4 slides for PD-L1 immunohistochemistry. These slides are required and will be shipped directly to HistoGeneX. See details in section 8.3.
2. Submit a representative tumor tissue block OR 20 unstained tissue section slides from such a block to AFB for correlative studies, if tissue is available. Block submission is strongly preferred.
3. If current disease is a recurrent or progressive lesion, also submit a representative tumor tissue block from the primary tumor resection OR 1 H/E stained slide + 10, 8 micron tissue sections for nucleic acid extraction and analyses from such a block to AFB, if it is available. Block submission is strongly preferred.
4. Whole blood in BCT tubes will be shipped to AFB. See details in section 9.1.
5. Whole blood in ACD and Heparin tubes will be shipped to OSU. See details in sections 9.2 and 9.3.

6. BIOSPECIMEN COLLECTION KITS

6.1. To facilitate the proper collection and shipping of all biospecimens, biospecimen collection kits and materials will be provided. The cost of the kit and shipping the kit to the site will be paid for. A pre-paid FedEx waybill is provided for shipping the kit with the biospecimens back to the AFB at Washington University in St. Louis, HistoGeneX, or the Clinical Flow Cytometry Laboratory at Ohio State University via priority overnight shipping.

6.2. Kits should be requested at least 10 working days in advance of the anticipated collection date. As many as 2 kits can be requested at one time. Since many of the collection materials (vacutainer tubes) have expiration dates, do not request kits more than 90 days prior to their anticipated use. **All kits must be requested using the AFT BioMS system.**

6.3. Kit contents and specific instructions for use of the kit are provided in the kit box and are available for download on the AFT BioMS webpage which is accessible via the AFT portal: https://alliancefoundationtrials.org. **Please return any used collection materials with the kit**.

6.4. Once a kit is received, **do not discard the outer cardboard overwrap**. The kit, containing biospecimens, is to be shipped back in the same box.

6.5. Please return all components of the kit, regardless of whether they have been used or not. Kits and kit components are recycled when possible, minimizing the kit cost.

6.6. Well in advance of collecting biospecimens, inspect the biospecimen collection kit to ensure that all components are present and not expired, particularly if the kit has been onsite for longer than 30 days.

6.7. Note that individual kit components that are expired, damaged, or missing cannot be replaced. The remedy is to order a complete, new kit. (Please note in your request that you are replacing an expired or damaged kit).

6.8. Please return all kits that have expired or missing components. Return the ENTIRE kit using the pre-paid FedEx waybill provided. DO NOT DISCARD kits that have missing or expired components. Recycling kits keeps the cost of kit materials to a minimum. Please note that all out-going and in coming kits are tracked, and sites that have requested many more kits than they have returned will be charged for non-returned kits.

6.9. If a biospecimen collection component (e.g. vacutainer collection tube) is missing, damaged, or expired, the institution may substitute a like-kind collection tube from their own supply. However, note that while some kit components are generic (EDTA tubes) others are highly specialized (Streck BCT tubes) and probably are not available at the institution.

6.9.1. Note that protocol requirements are based on blood volumes, not tube sizes. If the protocol requires the collection of 8 cc of whole blood, generally a 10 cc tube is provided in the kit for convenience. If desirable or necessary to collect 8 cc in 3 x 3 cc tubes (for example), that is permissible.

6.10. Please see **Section 10 – Biospecimen Shipping** for specific instructions on packaging biospecimens into the shipping kits for shipment to the biorepositories.

7. BIOSPECIMEN LABELING AND TRACKING

7.1. All research biospecimens (vacutainer tubes, tissue bags) MUST be labeled with the participant study number and patient initials (Last, First, Middle). Blood tubes should additionally be labeled with the date and time of collection.

7.2. Surgical pathology tissue blocks should not be labeled in any manner. The institutional surgical pathology number (e.g. “S16-1234”) and the individual block identifier (e.g., “A3”) should be readable on the block. If tissue sections are being submitted instead of the block, each tissue section slide should be labeled with the participant study number, the institutional block ID, and the slide serial section number (1, 2, 3, etc.). Provide a **de-identified** copy of the surgical pathology report, labeled only with the participant study number, corresponding to the blocks or slides submitted. See section 8 for additional details.

7.3. Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature. Do not try to label frozen vials.

7.4. Do not affix any labels to vials, slides, or tubes. Label the collection containers directly with a marking pen.

7.5. All biospecimens that are collected and sent to the AFT biorepository (AFB), Ohio State University (OSU), or HistoGeneX **must be logged and tracked in AFT BioMS**. The AFT BioMS system is a web-based application that tracks the collection and shipping of biospecimens. Once individual biospecimens are logged and ‘shipped’ in the AFT BioMS system, a packing manifest will be created by the system. This manifest must be printed out and must accompany all biospecimen shipments. To become familiar with the AFT BioMS system and for further information about training, access, and use, please contact the AFT BioMS Help desk at: 1-855-642-4667 or aftbiomshelp@email.wustl.edu. Note that the AFT BioMS system is similar

to but independent of the NCI BioMS application, which is used to manage biospecimens collected on NCI NCTN Alliance trials.

7.6. In the event that AFT BioMS cannot be accessed, please complete an AFT BioMS specimen manifest form, which can found here- https://cbmiapps.wustl.edu/confluence/display/AB/Forms

7.7. For unstained slide submission to HistoGeneX, download and complete the "HistoGeneX Sample Manifest" which can be found here- https://cbmiapps.wustl.edu/confluence/x/AoF9AQ. This form must be completed and emailed to Katrien.Vanloock@histogenex.com, Janice.Spohn@histogenex.com, and UStrials@histogenex.com prior to shipping.

8. TISSUE COLLECTION METHODS

8.1. Overview

8.1.1. Please refer to protocol-specific instructions for procedures related to actual tissue procurement from individual participants.

8.1.2. In order to be eligible for the study, all subjects must submit unstained tumor tissue slides to HistoGeneX for PD-L1 staining. Core needle or excisional biopsies, or resected tissue is required. FFPE cell pellets, alcohol-fixed specimens, fine needle aspirates, ascites fluid, pleural fluid, cytology specimens, or bone metastases are not acceptable.

8.2. Diagnostic Pathology Fixed Tissue Blocks

8.2.1. This protocol requests submission of ONE representative, diagnostic pathology, formalin fixed paraffin embedded (FFPE) tumor tissue block. Additionally, if available, ONE representative, diagnostic pathology, formalin fixed, paraffin embedded tumor tissue block from the original tumor resection should also be sent, in cases which present as recurrent or progressive lesions. FFPE cell pellets, alcohol-fixed specimens, fine needle aspirates, ascites fluid, pleural fluid, cytology specimens, or bone metastases are not acceptable.

8.2.2. Any clinical surgical pathology block that is submitted for research studies will not be exhausted or rendered unsuitable for future diagnostic use. Any clinical surgical pathology block that is submitted will be returned within ten working days of written request, when needed for clinical management or clinical trial enrollment for a specific patient. Otherwise, all blocks will be returned to the submitting institution when the correlative science study end points have been met.

8.2.3. In the event that an institution will not release a tumor tissue block, the institution may instead submit tissue sections, mounted and unstained to glass slides.

8.3. Unstained Slides from Diagnostic Fixed Tissue Blocks

8.3.1. At least 4 unstained tumor tissue sections containing at least 50 viable tumor cells, cut at 4 microns and provided on positively charged slides are **required** for PD-L1 immunohistochemistry.

8.3.2. In cases where institutions are unable or unwilling to submit the requested tissue block, a set of 20 unstained tissue slides may be sent as an alternative. Please follow the procedures below for submitting unstained tissue slides.

# of slides	Section thickness	Slide type	Purpose	Recipient Lab
4	4 micron	Positively Charged	PD-L1 immunohistochemistry (Required)	HistoGeneX
20	10 micron	Positively Charged	Correlatives (If tissue available and site unable or unwilling to send fixed tissue block)	AFB

8.3.3. Serial, tissue sections should be cut fresh (≤ 60 days prior to submission) from the appropriate FFPE tissue block. FFPE cell pellets, alcohol-fixed specimens, fine needle aspirates, ascites fluid, pleural fluid, cytology specimens, or bone metastases are not acceptable.

8.3.4. Cut sections at 4 or 10 micron thickness as indicated onto positively charged slides.

8.3.5. Ensure that each slide is labeled with the patient study number, the institutional block ID, and the slide serial section number (1, 2, 3, etc.).

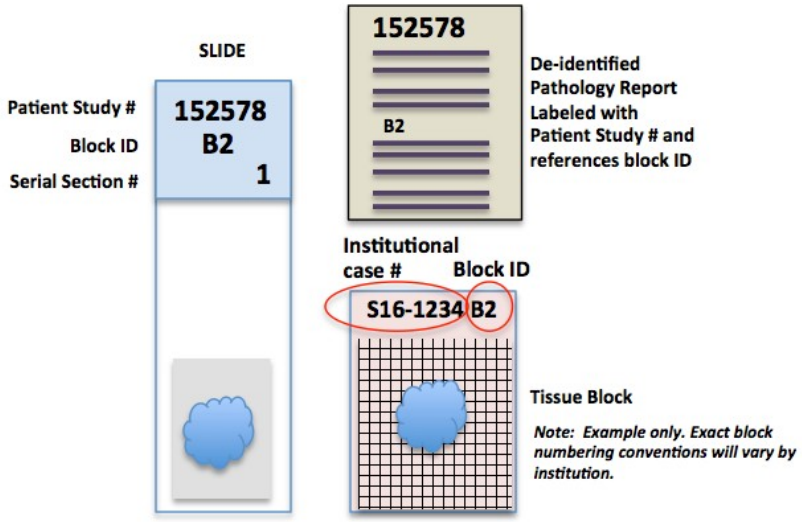
8.3.6. Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.

8.3.7. No adhesives or other additives should be used in the water bath.

8.3.8. Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.

8.3.9. When placing the sections onto the slides, ensure that the tissue is placed on the bottom third of the slide. Ensure that each serial section from the block is placed in the same orientation on each slide.

8.3.10. See figure below for proper mounting and labeling



8.3.11. The PD-L1 slides for HistoGeneX should be baked at 60°C ± 2°C with ventilation (no humidification) for 2 hours. However, the slides for AFB should be air-dried for 12-24 hours prior to shipping to AFB. **Do not oven dry slides for submission to AFB.**

8.3.12. Use the slide boxes provided in the kit for shipping slides. Slides should not be touching each other. Ensure that slides from only one patient are placed in one slide mailer.

8.3.13. Include a copy of a de-identified pathology report, labeled only with the patient study number with all slide submissions.

8.4. Tissue Sections

8.4.1. In cases where an institution is unwilling or unable to submit a tissue block and tissue is used solely for nucleic acid extraction, a single H/E stained slide for references and serial tissue sections (scrolls) from the same block may be submitted.

8.4.2. Cut and perform a routine H/E stain on a single section from the tumor tissue block. Be certain to label the stained slide using all of the conventions and guidelines outlined in section 8.3.

8.4.3. Cut a “ribbon” (“scroll”) of 10, 8 micron paraffin tissue sections. Place the ribbon of tissue directly into the tube provided or any other suitable container. Do not float the tissue ribbon or sections in a water bath. Label the tube of tissue following the guidelines outlined in section 8.3.

9. BLOOD COLLECTION METHODS

9.1. Plasma Nucleic Acid (Streck) Tube Processing

9.1.1. Collect 8 ml of blood into each of the Streck BCT tubes using standard venous phlebotomy. Invert tubes 10 times.

9.1.2. Store Streck tubes with whole blood at room temperature. Do not freeze or refrigerate the tubes. The tubes may be stored for up to 72 hours at ambient temperature before shipment. Ensure that the Streck tubes are shipped at ambient temperature to avoid freezing.

9.2. Whole blood- ACD tubes (no processing)

9.2.1. Collect 5 ml of blood into each of the ACD tubes using standard venous phlebotomy. Invert tubes 10 times.

9.2.2. Store ACD tubes with whole blood at ambient temperature until shipping. Do not freeze or refrigerate the tubes. **The tubes must be shipped within 24 hours of collection (e.g. Friday—Saturday collections or Holiday collections are not allowed).** Ensure that the ACD tubes are shipped at ambient temperature to avoid freezing.

9.3. Whole blood- Heparin tubes (no processing)

9.3.1. Collect 10 ml of blood into each of the heparin tubes using standard venous phlebotomy. Invert tubes 10 times.

9.3.2. Store heparin tubes with whole blood at ambient temperature until shipping. Do not freeze or refrigerate the tubes. **The tubes must be shipped within 24 hours of collection (e.g. Friday—Saturday collections or Holiday collections are not allowed).** Ensure that the heparin tubes are shipped at ambient temperature to avoid freezing.

10. BIOSPECIMEN SHIPPING

10.1. Overview

10.1.1. Please see the Directions for Use (DFU) document that is included in each kit, for specific directions on how to package and ship biospecimens. The DFU document is also available for download on the AFT BioMS webpage which is accessible via the AFT portal: (https://alliancefoundationtrials.org).

10.1.2. Place the original, completed copy of the AFT BioMS Packing Manifest in the kit. If sending tissue, include a copy of the de-identified surgical pathology report, labeled with the patient study number. Do not send specimens without a completed AFT BioMS Packing Manifest or substitute "AFT BioMS Downtime Form". Biospecimens cannot be accepted without this completed form.

10.1.3. **For unstained slide submission to HistoGeneX, download and complete the "HistoGeneX Sample Manifest" which can be found here- https://cbmiapps.wustl.edu/confluence/x/AoF9AQ. This form must be completed and emailed to Katrien.Vanloock@histogenex.com, Janice.Spohn@histogenex.com, and UStrials@histogenex.com prior to shipping.**

10.1.4. All biospecimens should be shipped on the same day that they are collected (Monday – Thursday). Biospecimens must be received by the recipient lab within 24 hours of collection. If collected biospecimens cannot be shipped on the same day that they are collected (e.g. Friday – Saturday or Holiday collections), please contact the AFB Program

Manager at 1-314-747-4402 for further instructions, at least 24 hours prior to anticipated collection.

10.1.5. **Do not ship on Friday, Saturday, Sunday or day before a nationally recognized holiday.**

10.1.6. Because paraffin tissue blocks or slides cut from such blocks may be requisitioned and received from the surgical pathology department at a different time than the day of procurement for other biospecimens, paraffin blocks or cut slides may be sent independently of other biospecimens.

10.1.6.1. There is no independent "kit" for the submission of paraffin blocks or slides.

10.1.6.2. Blocks and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.

10.1.6.3. During warm weather months, paraffin slides and blocks should be shipped in an insulated container that contains a refrigerant pack, to avoid heat > 25 degrees C (77 degrees F) that may melt paraffin and damage blocks and slides.

10.1.6.4. Blocks and slides may be shipped for standard overnight delivery according to institutional policies and using the preferred vendor.

10.2. Shipping to HistoGeneX

10.2.1. Enclose slide mailer containing unstained tumor tissue slides for PD-L1 immunohistochemistry within padded envelope or small Styrofoam cooler. Ship for PRIORITY OVERNIGHT DELIVERY using the pre-paid FedEx waybill provided. Samples can be received at HistoGeneX from Monday to Friday between 8 am and 2 pm.

Ship to:

HistoGeneX NV
Attn. Sample Reception Team- P0893
1331 W. 75th Street Suite 401
Naperville, IL 60540
Phone: +1-630-473-6575
E-mail: UStrials@histogenex.com

10.3. Shipping to OSU

10.3.1. Enclose ACD and Heparin tubes within blood tube mailer. Ship container for PRIORITY OVERNIGHT DELIVERY using the pre-paid FedEx waybill provided.

Ship to:

Dr. Gerald Lozanski
Clinical Flow Cytometry Laboratory
E303 Doan Hall
410 West 10th Avenue
Columbus, OH 43210-1218
Phone 614-293-8326

10.4. Shipping to AFB

10.4.1. Enclose specimens within the ambient shipper. Ship container for PRIORITY OVERNIGHT DELIVERY using the pre-paid FedEx waybill provided.

Ship to:

AFT Biorepository
c/o Siteman Cancer Center Tissue Procurement Core
Washington Univ. School of Medicine
425 S. Euclid Ave, Room 5120
St. Louis MO
63110-1005
Phone (314)-454-7615

11. AFB BIOSPECIMEN RECEIPT AND QUALITY ASSURANCE MEASURES

11.1. Upon receipt at AFB, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.

11.2. All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.

11.3. Each individual biospecimen will receive and be physically labeled with a unique biospecimen identifier, associated with the biopsy control number in the TPC informatics system.

11.4. Upon receipt, all physical biospecimens received will be reconciled with what is recorded on the AFT BioMS packing manifest. Any discrepancies noted will be communicated to the AFB Program Manager who will contact the submitting site for reconciliation.

11.5. Upon receipt, any biospecimen received that is not in appropriate physical condition (broken vials, frozen samples that are thawed, ambient samples that are frozen) will be reported to the AFB Program Manager, who will contact the submitting site for reconciliation.

11.6. Aliquoted biofluids will be stored under liquid nitrogen vapor.

11.7. All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol principal investigator.

12. DOCUMENT HISTORY

VERSION	DESCRIPTION AND JUSTIFICATION OF CHANGE	AUTHOR	EFFECTIVE DATE
3.0	Added additional study time points	PAA	12-Sept-2019
2.0	Reformatted to AFT Template Updated contact information for AFB Direct sites to portal for DFU	PAA	19-June-2018
1.2	Clarify shipping requirements for HistoGeneX	PAA	07-Nov-2017
1.1	Corrections to HistoGeneX address Clarified unstained slide protocol	PAA, PP	25-July-2017
1.0	New	PAA	09-May-2017