

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen collection for Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions	Version No: 1.2	Effective Date: 11/19/2021
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## CORRELATIVE SCIENCE PROCEDURE MANUAL

### 1. Purpose

This document describes the procedures required for the collection, shipping, and processing of biospecimens that are being submitted for patients enrolled or registered on A211901. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the Alliance Biorepository at Mayo Clinic (ABMAYO) or 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 A211901 biospecimen collection, processing, and submission, including staff at satellite institutions.

### 2. Scope

This document applies to all biospecimens collected specifically for the A211901 clinical trial study. Please refer to the trial protocol-specific language for additional details regarding eligibility, participant enrollment, and data submission. **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 may be found on the Alliance website and CTSU.**

### 3. Definitions

Term	Definition
ABMAYO	Alliance Biorepository at Mayo Clinic

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#### 4. Contact Information

- 4.1** For questions and problems related to protocol administration, eligibility, patient registration, and data submission, relevant contact information is listed on protocol pages 1 and 2.
- 4.2** For information on using the BioMS system, please refer to the ‘Help’ links on the BioMS webpage to access the online user manual, FAQs, and training videos. To report technical problems, such as login issues or application errors, please contact: 1-855-55-BIOMS or [bioms@alliancencn.org](mailto:bioms@alliancencn.org). For assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancencn.org](mailto:bioms@alliancencn.org).
- 4.3** For all other questions regarding biospecimen procurement and shipping procedures, please contact:
- ABMAYO**
- Katie Halverson  
Phone: 1-507-293-7147  
Email: [halverson.katie@mayo.edu](mailto:halverson.katie@mayo.edu)

#### 5. Site Preparation

- 5.1** Please refer to A211901 protocol document for any specific requirements related to patient enrollment, registration, and regulatory compliance.
- 5.2** Please ensure that you have the appropriate login credentials and can successfully access the BioMS application. The BioMS application is used for both requesting biospecimen collection kits and for logging the collection and shipment of biospecimens to the Alliance Biorepository at Mayo Clinic. For training and assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancencn.org](mailto:bioms@alliancencn.org).

#### 6. Collection Schema

The following biospecimens are to be collected at each of the time points listed in the table below. Please refer to individual biospecimen collection and processing methods, and specific shipping procedures that are detailed in this manual.

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Time Point	Kit (Y/N)	Biospecimen	Quantity	Collection / Processing Method	Shipping / Recipient Lab	Notes
<b>Mandatory for patients registered to A211901</b>						
6 months post quit date	Y	Urine	1 x 5 ml	Urine (9.1)	Ambient / ABMAYO (11.3)	1
<b>For patients registered to A211901 Biobanking</b>						
Baseline	N	Whole Blood (EDTA tube)	1 x 10 ml	Whole blood EDTA (10.1)	Cool Pack / ABMAYO (11.3)	2, 3

**Notes:**

1. Urine required only if participants self-report cessation from combustible cigarettes. Urine is required regardless of self-reported vaping or nicotine replacement therapy (NRT) use. Cotinine will be used in the analysis if there is no self-report of vaping or NRT and anabasine will be used if patients do self-report these things. Participants who self-report cessation and do not return at 6 months post-quit date for the urine assessment will be deemed smokers.
2. Collection is optional for patients but requires all sites offer to patients to consent. Please see protocol-specific consent documents.
3. It is preferred that specimen is drawn on the day of randomization / registration, but it can be submitted at a later time when patients are on study.

## 7. Biospecimen Collection Kits

### 7.1 Urine Specimens

- 7.1.1 To facilitate the proper collection and shipping of urine specimens to ABMAYO, biospecimen collection kits and materials will be provided. The cost of the kit and shipping the kit to the site will be paid for. The institution is expected to pay for return shipping of the kit with the biospecimens to ABMAYO via priority overnight shipping.
- 7.1.2 Kits should be requested at least 10 working days in advance of the anticipated collection date. As many as 3 kits can be requested at one time. Do not request kits more than 90 days prior to their anticipated use. All kits must be requested by using the BioMS system.
- 7.1.3 Well in advance of collecting biospecimens, inspect the biospecimen collection kit to ensure that all components are present, particularly if the kit has been onsite for longer than 30 days.
- 7.1.4 If a biospecimen collection component is missing or damaged, the institution may substitute a like-kind collection component from their own supply.

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## 7.2 Whole Blood Specimens (EDTA)

**7.2.1** There are no “kits” provided for submission of whole blood specimens in EDTA tubes for this study. Sites are responsible for acquiring the materials for collection and shipping of these specimens to ABMAYO.

## 8. Biospecimen Labeling and Tracking

- 8.1** All research biospecimens **MUST** be labeled with the Alliance study number (A211901), Alliance patient ID number, patient initials (Last, First, Middle), the date and time of collection and specimen type (i.e. “urine,” “whole blood”). Specimen labels must match BioMS records.
- 8.2** Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature.
- 8.3 Do not affix any labels to vials or tubes.** Label the collection containers directly with the marking pen.
- 8.4** All biospecimens that are collected and sent to ABMAYO must be **logged and tracked in BioMS** under A211901. Do not send samples in which the patient has not been registered onto the study. The BioMS system is a web-based application that tracks the collection and shipping of biospecimens. Once individual biospecimens are logged and ‘shipped’ in the 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 BioMS system and for further information about training, access, and use, please contact the BioMS Help desk at: 1-855-55-BIOMS or [bioms@alliancencn.org](mailto:bioms@alliancencn.org).
- 8.5** In the event that BioMS cannot be accessed, please complete a BioMS Specimen Log and Shipping Manifest form which can be found here- <http://tinyurl.com/alliance-bioms-contingency>.

## 9. Urine collection Methods

### 9.1 Urine (No Processing)

- 9.1.1** Instruct patients to collect approximately 5 ml of urine into a clean specimen cup.
- 9.1.2** Urine may be held at ambient temperature for up to 48 hours prior to shipping. Urine should be shipped to ABMAYO at ambient temperature. **It must be received within 3 days (72 hours) of collection.**

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## 10. Blood Collection Methods

### 10.1 Whole Blood EDTA (No Processing)

**10.1.1** Collect whole blood by standard venous phlebotomy technique into the EDTA tube. Invert tube 10 times.

**10.1.2** Store EDTA tube with whole blood at 4 degrees Celsius (i.e. refrigerated) until shipping. Do not freeze the tube. **The tube may be stored for up to 72 hours at refrigerated temperature before shipment. If blood must be collected on Friday, it can be shipped on Friday for Saturday delivery. Ensure that the EDTA tube is shipped with a refrigerant pack to ensure proper temperature and to avoid freezing.**

## 11. Biospecimen Shipping

**11.1** Place the original, completed copy of the BioMS packing manifest in the shipment. Do not send specimens without a completed BioMS Packing Manifest or substitute “BioMS Downtime Form.” Biospecimens cannot be accepted without this completed form.

**11.2** If biospecimens cannot be shipped within the timelines indicated in **sections 9.1.2 or 10.1.2**, please contact appropriate personnel listed in **section 4.3** for further instructions, at least 24 hours prior to anticipated collection.

### 11.3 Shipping to ABMAYO

Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor. Ship specimens to ABMAYO on Monday through Friday only. Do not ship on Saturdays or on the day before a national holiday.

Ship to:

Alliance Biorepository at Mayo Clinic- BAP Freezer

ST-SL-16

150 Third Street SW

Rochester, MN 55902

Phone: 507-538-0602

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## 12. ABMAYO Biospecimen Receipt and Quality Assurance Measures

- 12.1** All biospecimens sent to ABMAYO will be accessioned into the informatics system BioMS, at ABMAYO Research Laboratory Information Management System (RLIMS) which interfaces with BioMS.
- 12.2** All biospecimens received at the ABMAYO will be logged, associated, and tracked by the patient study ID number.
- 12.3** Upon receipt, all physical biospecimens received will be reconciled with what is recorded on the BioMS packing manifest. Any discrepancies noted will be communicated to submitting site for reconciliation.
- 12.4** 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 Program Manager, who will contact the submitting site for reconciliation.
- 12.5** All biospecimens submitted to ABMAYO will remain in storage until exhausted. In the event the patient withdraws consent, the specimens will be disposed/returned according to Alliance Policy and Procedure Chapter 11.

## 13. Document History

Version	Description and Justification of Change	Author	Effective Date
1.2	Corrected Mayo phone number	PAA	11/19/2021
1.1	Updated Mayo contact information	PAA	08/12/2021
1.0	New	PAA, DN	05/27/2021