

U54 SCENT

SSW-CTS-011 v.3.0

PI: Hartwig

IRB #: Pro00109991

CoreResearch@Duke: STY-22-00071

Signed:	Date:
Signature	
Mary-Beth Joshi, M.P.H. Director, Duke Substrate Services Core and	d Research Support (SSCRS)
Signature	
Study Team Lead	



Document History



Title / Version	<u>Replaces</u>	Effective Date	<u>Description of Change</u>
SSW-CTS-011 V 1.0	N/A		Initial SSCRS SSW
SSW-CTS-011 V 2.0	SSW-CTS-011 V 1.0		A. Updated tissue processing for Donor Cohort B. Removed tissue processing from Autopsy and Surgical Resection Cohorts
SSW-CTS-011 V 3.0	SSW-CTS-011 V 2.0	A	A. Updated processing of Tissue Fragments



Table of Contents



- 1. Study Team & SSCRS Study Contacts
- 2. Responsibilities
- 3. Enrollment of Subjects into CoreResearch@Duke
- 4. Collection Event Notification Workflow
- 5. Sample Quality Considerations
- 6. Study Time Points & Collection Kit Configuration
- 7. Sample Processing Workflow
- 8. Sample Labelling



1. Contact Information



Study Team: This refers to the PI and his/her study coordinators

and laboratory staff

Study Team Contacts:

Name: Sarah Casalinova

Office Number: 919-613-5621

Pager: 919-970-8211

Email: sarah.casalinova@duke.edu

Study Team Contacts:

Name: Megan Griffin (BRPC)
Office Number: 919-684-2555

Pager: 919-970-7922

Email: megan.griffin624@duke.edu

SSCRS Team: This refers to the laboratory staff of the Substrate

Services Core and Research Support

SSCRS Team Contacts:

Email: <u>surgerysubstrate@dm.duke.edu</u>

Pager: 919-970-0705 Lab: 919-684-2294



2. Responsibilities: Subject Enrollment & Data Entry



Activity	Responsible Party
Enrollment of Subjects into CoreResearch@Duke	SSCRS Team
Sample Receipt into CoreResearch@Duke	SSCRS Team



2. Responsibilities: Notifications, Sample Collection & Sample Receipt



Activity	Responsible Party
Label Parent Sample - patient id, date and time of collection	Study Team Clinical Staff
Sample Transport Form or Equivalent	Study Team Clinical Staff
Sample Collection & monitoring for sample collection	Study Team Clinical Staff
Notification of sample collection ready for pickup or impending delivery	Study Team Clinical Staff
Acknowledgement of sample collection Notification	SSCRS Team
Sample Delivery after notification of sample collection	Study Team Clinical Staff
Review of Sample & Documentation Upon Receipt	SSCRS Team
Notification to Study Team of Sample Receipt and request for any missing documentation	SSCRS Team



2. Responsibilities: Data Requests



Activity	Responsible Party
Submit requests for data by completing the form located at https://redcap.duke.edu/redcap/surveys/?s=WA3KH7A483	Study Team
Fulfill requests for data within 7 – 10 business days.	SSCRS Team



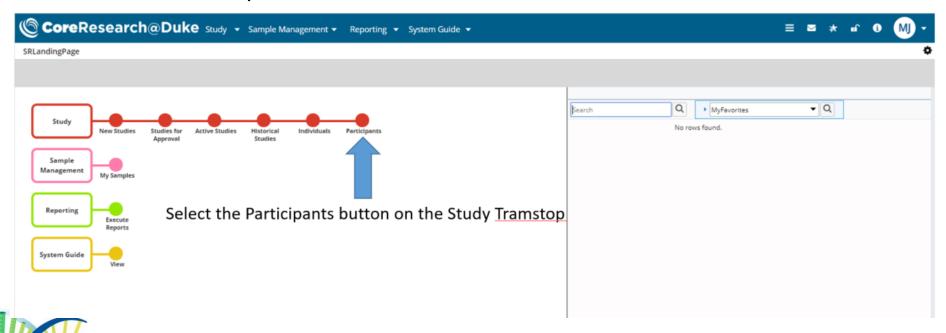
3. Enrollment of Subjects into CoreResearch@Duke



Go to https://coreresearch.duke.edu/

Log in using your Net ID and password

When you have logged into CoreResearch, Scroll to the bottom of the page to a drop down menu and select "study coordinator"



Subjects will be enrolled into CoreResearch@Duke by SSCRS Team

3. Enrollment of Subjects into CoreReserach@Duke



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	Family/Last Name			
	Gender *	▼	Date of Birth	#

3. Enrollment of Subjects into CoreResearch@Duke



Subjects will be enrolled into CoreResearch@Duke by SSCRS Team All yellow highlighted sections must be Enroll Participant OK * 🛃 Close completed ∧ Enroll Participant Study Select: STY-22-00071 Study ID Study Name TOP 1901 Select: Duke University Duke University(SS-00000527) > Study Plan Name TOP 1901 Cohort ID * Select Specific Cohort -All Participants ∨ Z Institution * Institution Name Duke University Health ! Select: Duke University Health System Individual Duke Medicine MRN Non-Duke Individual ID Individual ID Given/First Name Middle Name Family/Last Name Date of Birth Gender EMR Rac **EMR Ethnicity** Species Strain Enter the same External Participant ID in both places. **External Participant ID** Enrollment Date Time * Given/First Name Middle Name Family/Last Name Gender * ate of Birth **NIH Race** NIH Ethnicity Enter the date and time. (the actual **Enter Unknown** time does not need to be accurate. & Research Support for Gender

4. Sample Collection Workflow:



Sample Collection Day / Delivery

Study Team will notify SSCRS Staff by paging 970-0705 with the following info: "U54 SCENT"; Expected Delivery Time, Call Back #

Study Team schedules the delivery on Substrate Services Calendar: Send a meeting/calendar invite to surgerysubstrate@duke.edu for the Date & time of the expected delivery.



SSCRS Staff will return the page acknowledging notification of impending sample delivery.



The Study Team will deliver the sample between the hours of 8:00am and 6:00pm Monday -Friday.



SSCRS Staff will process samples



Automated email notification will inform the Study Team the samples were received.



5. Sample Quality Considerations:



Quality Begins Before Samples Arrive at SSCRS

- <u>Timely notification</u> of sample collection is essential for ensuring the samples are processed as quickly and efficiently as possible
 - i.e.. <u>Do not hold</u> blood samples or tissue samples for cell isolation until the end of surgery. Contact SSCRS at the time of the sample collection completion
 - Delays in sample processing may negatively impact the quality and integrity of the sample.
- **ALL Collection Containers** must be labeled with a subject identifier that can be matched to the accompanying Sample Transport Form.
- Sample Transport Form
 - Information of Sample Transport Form must match the information on each collection container
 - The following elements must be completed to ensure timely processing with the SSW guidelines
 - Subject Identifier
 - Collection Visit name Must match what is listed in the SSW
 - Collection Date
 - Collection Time



5. Sample Quality Considerations:



- Sample rejection Every attempt will be made to process samples, however
 - Volume of blood is not sufficient for PBMC processing (per approved SSW). However, plasma will be isolated whenever possible
 - If sample received in SSCRS is damaged or excessively dirty containers may be rejected due to safety concerns for SSCRS staff and/or will contaminate processing equipment. For example:
 - Broken sample collection containers
 - Sample has come out of the primary collection container into the secondary container
 - Samples are expected to arrive with subject identifiers on <u>each</u> collection container. Unlabeled samples will be rejected.
 - Any other sample rejections must be approved by the SSCRS Manager, SSC-S0004



6. Study Collections



Lung samples will arrive from 3 different cohorts. **Autopsy Tissue Surgical Resection Tissue Donor Tissue** Whole lungs will be Lung will go to Lung will go to delivered by courier to **BRPC** for grossing **BRPC** for grossing SSCRS for grossing. Whole Blood will be sent Normal lung tissue will be to SSCRS to process for **PBMC** and Plasma collected from each lobe:

FFPE

OCT

Snap Freeze

Multiome Assay

Sample Fragments for



6. Study Time Points

& Collection Kit Configuration



Donor Cohort
Collection Time point

Procurement

Surgical Resection Cohort Collection Time point

Surgical Resection

Autopsy Cohort
Collection Time point

Procurement

Time Point	Sample Type	Volume	# Expected	Process For:	SOP
Donor Cohort Procurement	Whole Lungs	N/A	N/A	FFPE with H&E, OCT, Snap Freeze Sample fragments for Multiome Assay	SSC-A0025 Study Specific
Surgical Resection Cohort	f(X(1))		PBMCs & Plasma	SSC-A0020	
Surgical Resection	Purple-Top (EDTA)	10.0 mL	2	Plasma	SSC-A0007

Collection Kits are provided by the Study Team.



7. Sample Processing Workflow –

Donor Tissue – Whole lungs



Tissue, From Honor Bridge

Collect a sample from each lobe and process per standard operating procedures for the following:

10% NBF
1 per lobe –
5 FFPE samples

FFPE Immediate H&E (for Carolyn Glass) OCT 1 per lobe – 5 OCT samples

Snap Freeze

3 per lobe – 15 snap frozen samples

Store @ -80°C

Tissue Fragments

3 cryovials per lobe each with 3-4 fragments – 15 total cryovials

- Fragments are to be collected from each lobe of the lung.
- Collect tissue fragments the size of a piece of rice, 9-12 pieces per lobe.
- Place 3 4 fragments into each of 3 cryovials, for a total of 15 cryovials.
- Add 1mL of freezing media to each cryovial. (Freezing Media is provided)
- Place cryovials into a CoolCell and Step-down freeze @ -80°C >14 Hr.
- Store @ -150°C or below

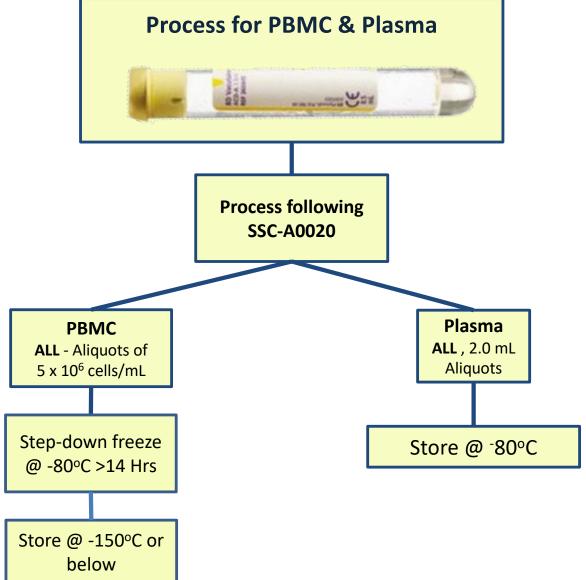


7. Sample Processing Workflow –

Surgical Resection Cohort –

3, 8.5 mL, Yellow-Top ACD Tubes





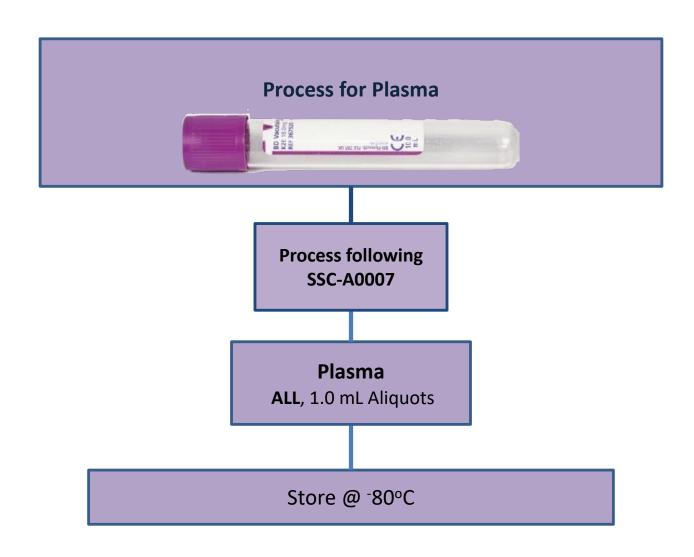


7. Sample Processing Workflow –

Surgical Resection Cohort –

Two, 10.0 mL, Purple-Top EDTA Tubes







7. Sample Labelling

(Representative Examples)



