



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 Research Support (SSCRS)

Signature

Study Team Lead

Document History



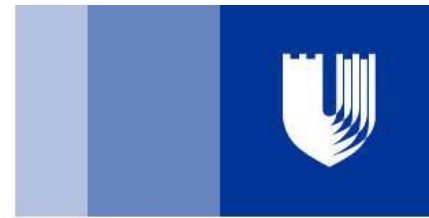
<u>Title / Version</u>	<u>Replaces</u>	<u>Effective Date</u>	<u>Description of Change</u>
SSW-CTS-011 V 1.0	N/A		Initial SSCRS SSW
SSW-CTS-011 V 2.0	SSW-CTS-011 V 1.0		A. Updated tissue processing for Donor Cohort B. Removed tissue processing from Autopsy and Surgical Resection Cohorts
SSW-CTS-011 V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

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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: surgerysubstrate@dm.duke.edu
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



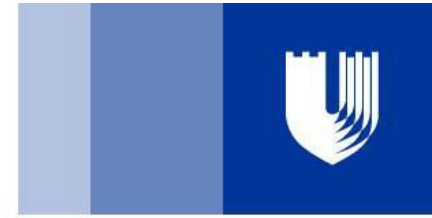
Activity	Responsible Party
Label Parent Sample - patient id, date and time of collection	Study Team Clinical Staff
Sample Transport Form or Equivalent	Study Team Clinical Staff
Sample Collection & monitoring for sample collection	Study Team Clinical Staff
Notification of sample collection ready for pickup 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

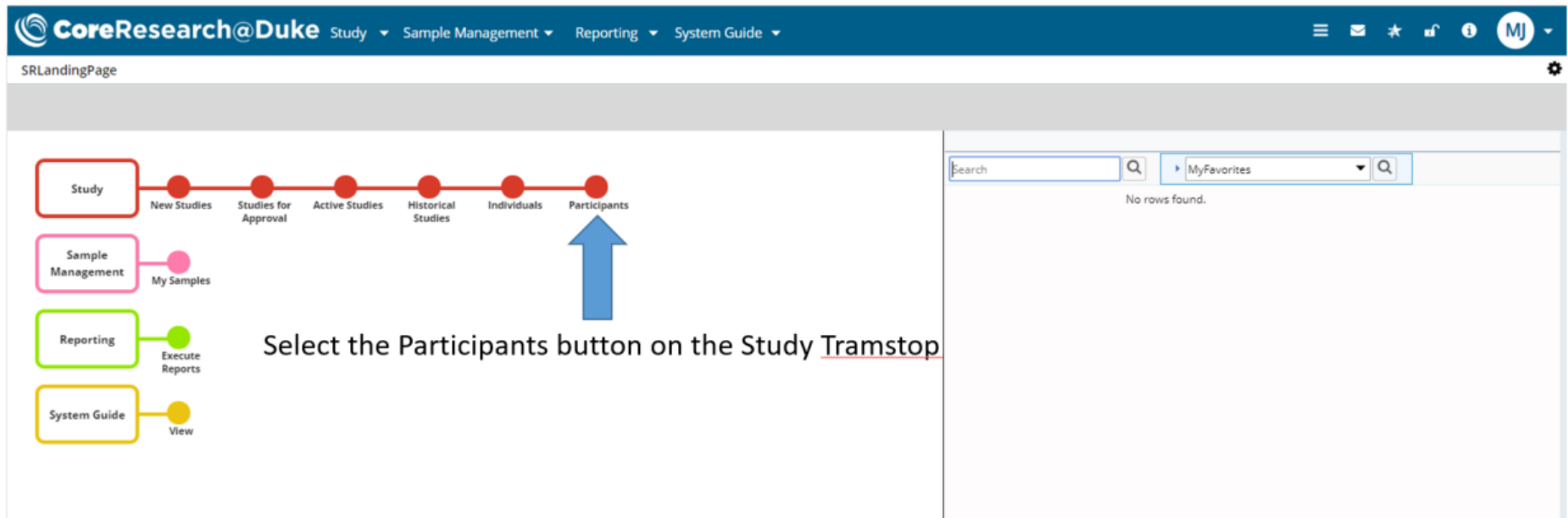
3. Enrollment of Subjects into CoreResearch@Duke



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

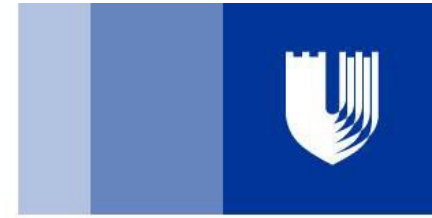
Log in using your Net ID and password

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 SSCR Team

3. Enrollment of Subjects into CoreResearch@Duke



CoreResearch@Duke Study Sample Management Reporting System Guide

Participant List

New Studies | Studies for Approval | Active Studies | Historical Studies | Individuals | Participants

Edit List Control Enroll Withdraw Complete Update Version Add Visit Workflow Other Tasks

By Study Name Show Advanced Search

Select "Enroll"

This "Enroll Participant" page will load

CoreResearch@Duke Estimate Management Projects Request For Service Manage Services

Enroll Participant - Google Chrome

coreresearch.duke.edu/CR/rc?command=page

Enroll Participant OK Close

Enroll Participant

Study

Study ID * Site ID * Cohort ID * Institution *

Study Name Study Plan Name Institution Name

Individual

Duke Medicine MRN Non-Duke Individual ID

Individual ID

Given/First Name Middle Name

Family/Last Name

Gender Date of Birth

EMR Race EMR Ethnicity

Species Strain

Participant

External Participant ID Enrollment Date Time *

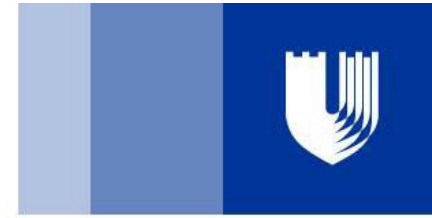
Given/First Name Middle Name

Family/Last Name

Gender * Date of Birth

NIH Race NIH Ethnicity

3. Enrollment of Subjects into CoreResearch@Duke



All yellow highlighted sections must be completed

Subjects will be enrolled into CoreResearch@Duke by SSCRS Team

- Select: STY-22-00071
- Select: Duke University
- Select Specific Cohort
- Select: Duke University Health System

Enroll Participant [OK] [Close]

Enroll Participant

Study	
Study ID *	Study Name
Site ID *	Study Plan Name
Cohort ID *	
Institution *	Institution Name

Individual	
Duke Medicine MRN	Non-Duke Individual ID
Individual ID	
Given/First Name	Middle Name
Family/Last Name	
Gender	Date of Birth
EMR Race	EMR Ethnicity
Species	Strain

Participant	
External Participant ID	Enrollment Date Time *
Given/First Name	Middle Name
Family/Last Name	
Gender *	Date of Birth
NIH Race	NIH Ethnicity

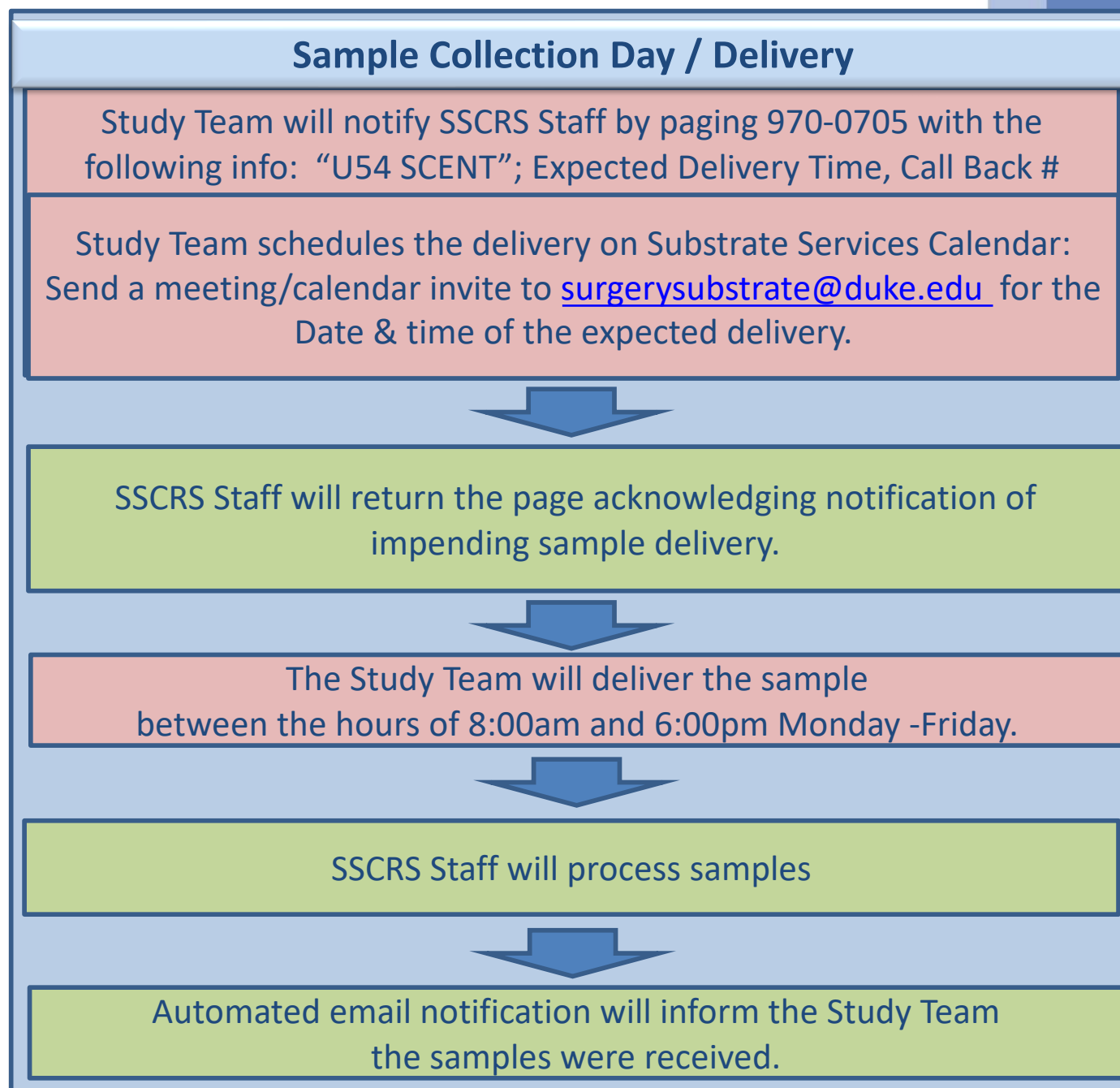
Enter the same External Participant ID in both places.



Enter Unknown for Gender

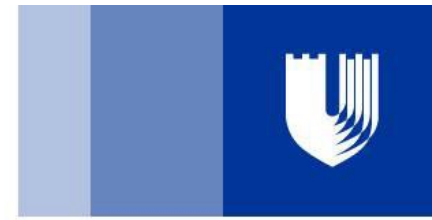
Enter the date and time. (the actual time does not need to be accurate.)

4. Sample Collection Workflow:



5. Sample Quality Considerations:

Quality Begins Before Samples Arrive at SSCRS



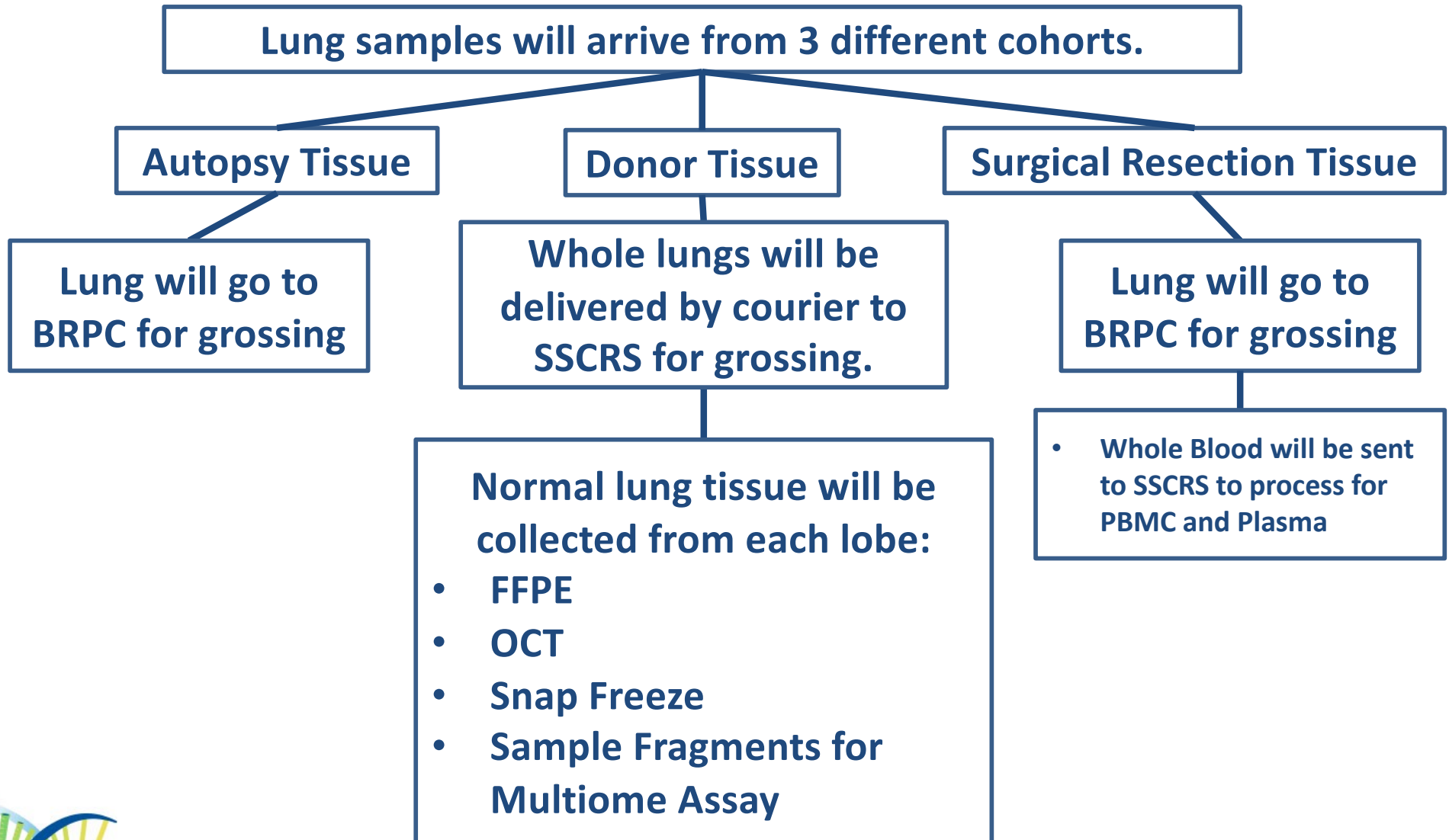
- **Timely notification** of sample collection is essential for ensuring the samples are processed as quickly and efficiently as possible
 - i.e.. **Do not hold** blood samples or tissue samples for cell isolation until the end of surgery. Contact SSCRS at the time of the sample collection completion
 - 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 each collection container. Unlabeled samples will be rejected.
 - Any other sample rejections must be approved by the SSCRS Manager, SSC-S0004

6. Study Collections



6. Study Time Points & Collection Kit Configuration

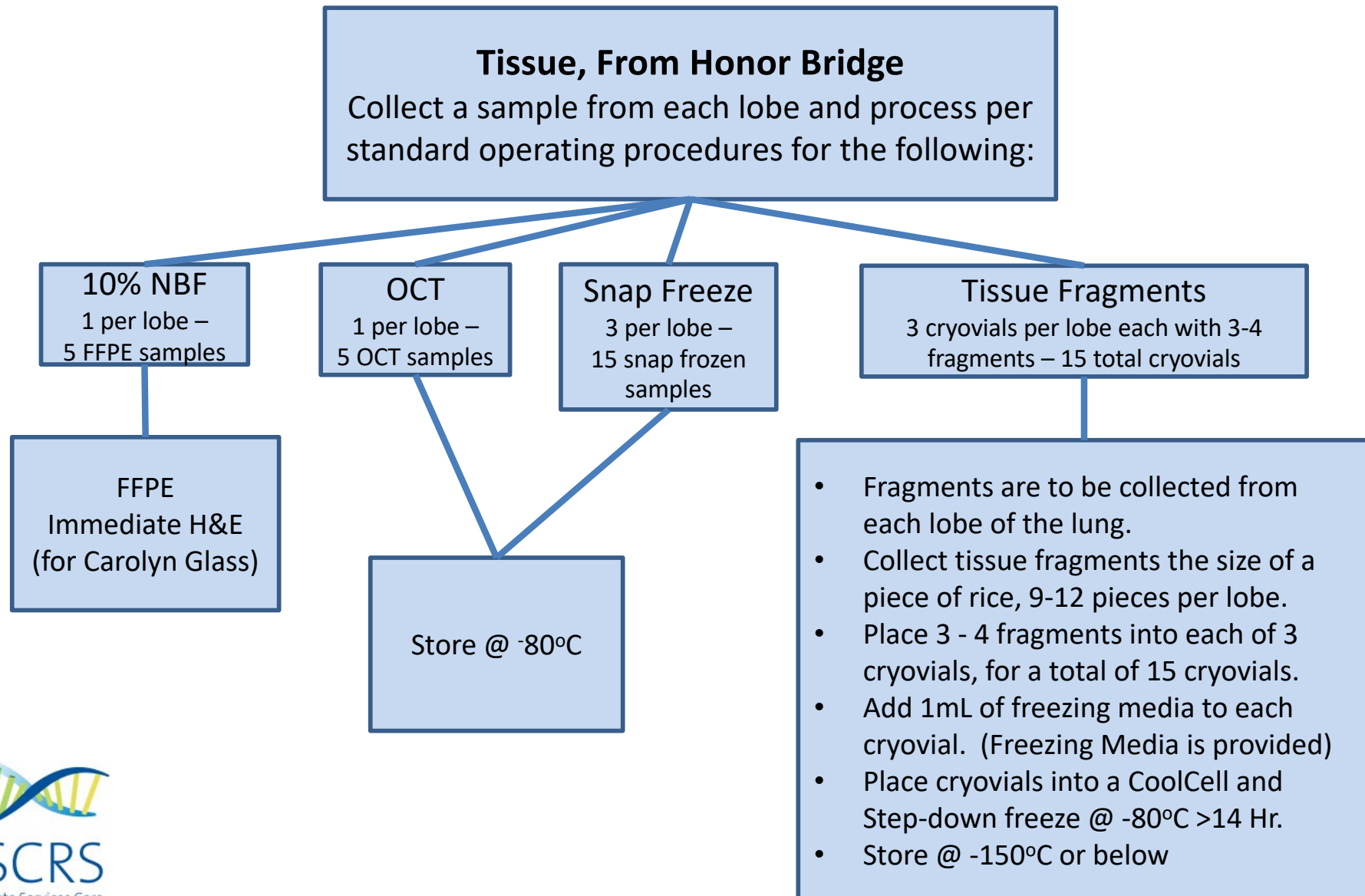
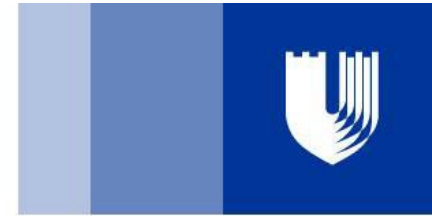


Donor Cohort Collection Time point	Surgical Resection Cohort Collection Time point	Autopsy Cohort Collection Time point
Procurement	Surgical Resection	Procurement

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 Surgical Resection	Yellow-Top (ACD)	8.5 mL	3	PBMCs & Plasma	SSC-A0020
	Purple-Top (EDTA)	10.0 mL	2	Plasma	SSC-A0007

Collection Kits are provided by the Study Team.

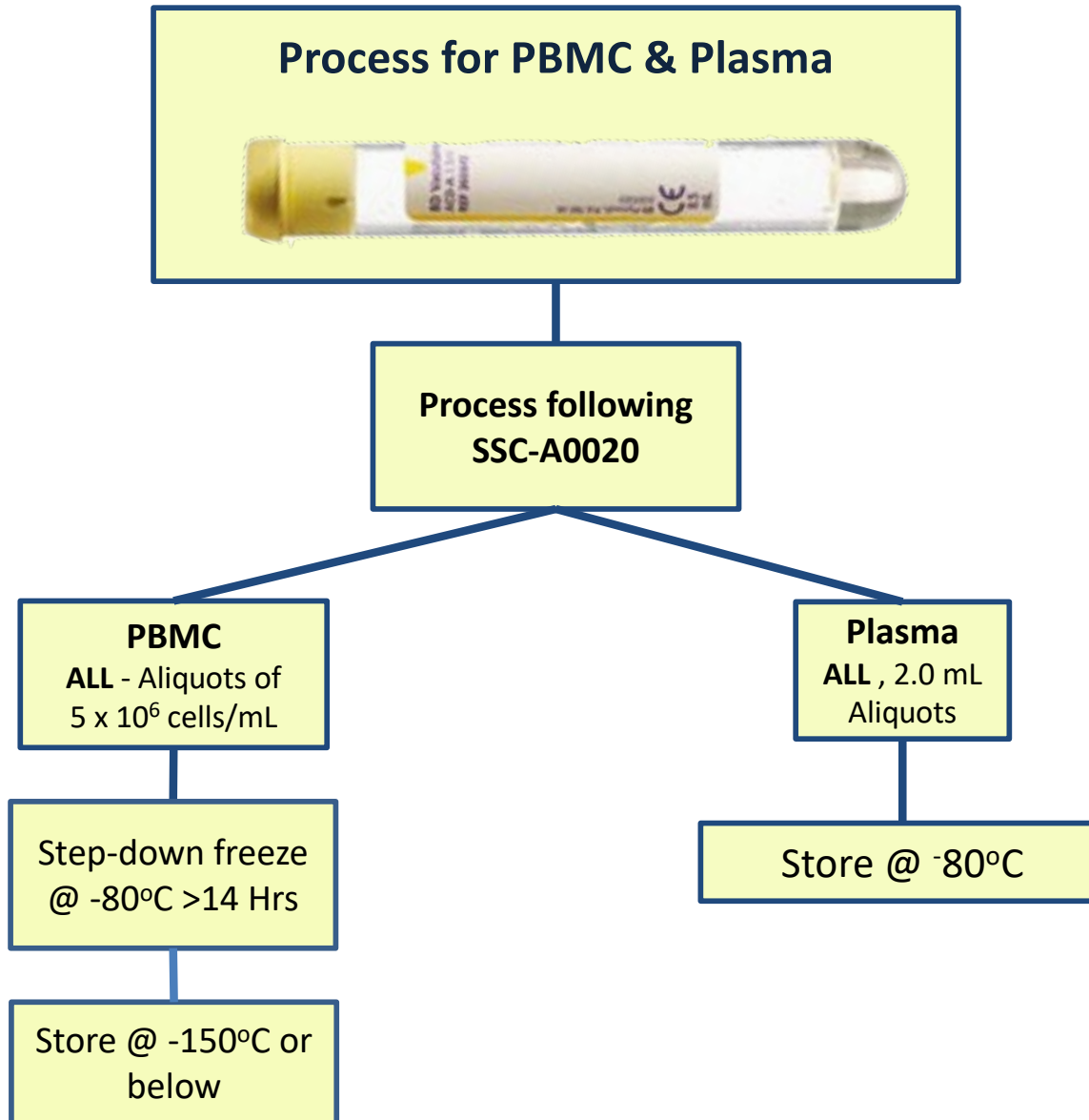
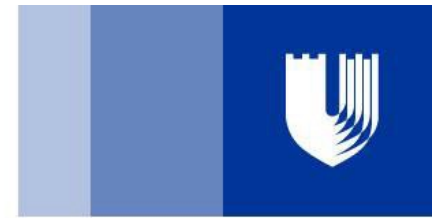
7. Sample Processing Workflow – Donor Tissue – Whole lungs



7. Sample Processing Workflow –

Surgical Resection Cohort –

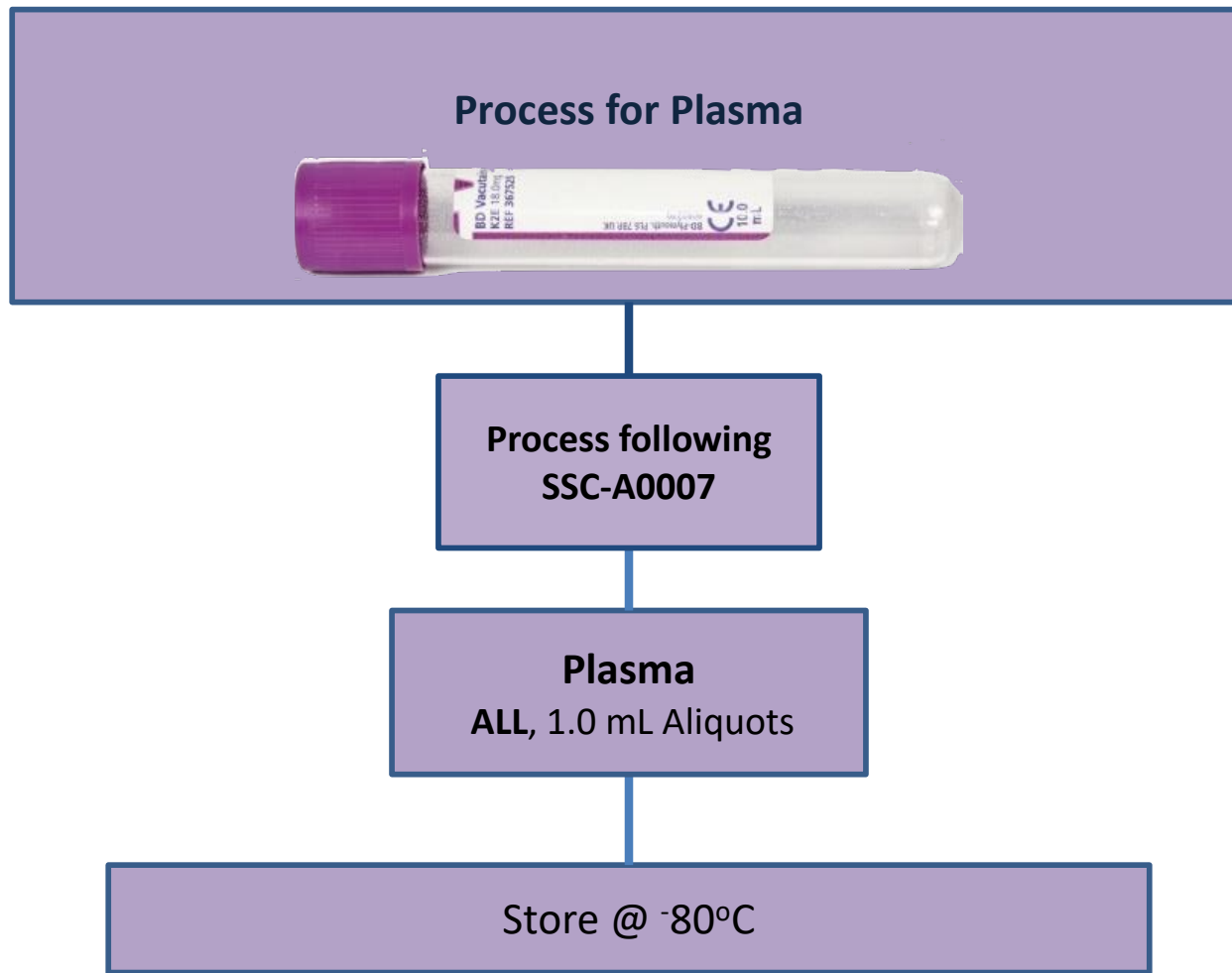
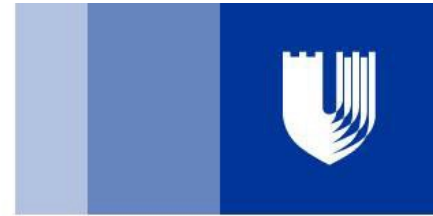
3, 8.5 mL, Yellow-Top ACD Tubes



7. Sample Processing Workflow –

Surgical Resection Cohort –

Two, 10.0 mL, Purple-Top EDTA Tubes



7. Sample Labelling

(Representative Examples)

