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**CTSI Biorepository and Laboratory Services (BLS)
BioNet Specimen Procurement Agreement**

Project Title: SenNet Liver Collection Protocol

PI:	Sayeed Ikramuddin & Laura Niedernhofer
CTSI Project #:	30108
OnCore #:	Liver Collection Study# SURG-2021-30108 Adipose Study# SURG-2020-28633
IRB #:	Liver Collection Study IRB# 00013764 Profiling of Adipose Study IRB# 00009134
Service Level:	Partial
Pathology Report Provided By BioNet:	No
After-Hours Authorization:	No

Material Group:	Material Type:	Material Modifier:	Preservation:	Quantity:	Notes:
Tissue	Liver	Normal	FFPE and OCT	2 biopsy cores/wedge	
Tissue	Adipose	Normal	FFPE, OCT, FF, fresh in media	5-10g	
Biofluid	Blood	Normal	EDTA lavender top tubes	3 x 5mL	Processing by TTL Bionet will provide 2 x 10mL EDTA tubes until study team is able to order

BLS Service Divisions Involved:

- ☒ BioNet (Prospective Specimen Procurement)
- ☒ Laboratory Network (Blood Processing)
- ☐ Repository
- ☒ Histology Laboratory
- ☐ Digital Imaging

Interventional Radiology Biopsy Project:

- ☒ Standard of Care + Research Procedure (Surgical Pathology Exam Will Be Ordered)
- ☐ Research Only Procedure (Surgical Pathology Exam Will Not Be Ordered)
- ☐ Cytology Adequacy Assessment Needed for Research (Must Be Set-Up Directly With Cytology)

Research Team Contacts:

Name	Email	Phone	Pager
Elizabeth Thompson	thom4573@umn.edu	952-688-3582	
Mickayla DuFresne-To	dufre050@d.umn.edu	651-707-4291	
Shannon Jannatpour	sjannatp@umn.edu		
Areeba Qaisar	qaisa005@umn.edu		

Allison Wolf	wolfx494@umn.edu		
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1. **Patient Identification:** As soon as a patient is scheduled, the research team will email bionet@umn.edu a completed Specimen Procurement Request Form.
2. **Patient Consent:** Researcher consents. The original signed consent form will be placed in the patient chart and scanned into Epic. BioNet will verify consent in Epic. If the consent is not scanned in EPIC before the procedure, the researcher will provide BioNet a copy direct (e-mail or hard copy).
3. **Collection Supplies:** All supplies will be delivered to the BioNet office (Mayo C338) at least one day before the procedure and appropriately labeled with researcher name and CTSI Project #.

Collection Kit Component	Provided By
PBS	Study team
Media: DMEM + antibiotics	Study team
Media tubes (x3 per collection)	Study team
10% Formalin	BioNet
FFPE cassette x 5	Bionet
Specimen container	Bionet
OCT compound	Bionet
OCT mold x 4	Bionet
OCT quick freeze box	Bionet
Liquid nitrogen vapor	Bionet
Cryovials x 3	Bionet
Collection kit containing 10 mL EDTA blood tubes x 2	Bionet (until study team is able to provide 3 x 5mL EDTA tubes)

4. Procurement and Processing:

Tissue: Limitation: procedures involving liver collection should be scheduled at East Bank hospital in order to accommodate short transit/processing time. Adipose only collections are permissible at the CSC, and the study team understands this may result in longer processing times. Tissue at the CSC should be kept cold (4C or on ice) and transported in solution (PBS or media). Morning procedures are ideal for both East Bank and CSC collections.

Liver (only collected at East Bank):

1. 2 liver biopsy cores or one liver wedge will be collected by surgeon and placed in PBS.
2. The location of the tissue collection will be recorded by the surgeon.
3. BLS will be paged by OR for immediate specimen pickup. BLS will pick up specimen and request BioNet Research Specimen Order.

If Liver is collected as cores:

Core 1:

1. BLS will take one core out of the PBS and place it in a formalin jar.
2. BLS will tape a labeled FFPE cassette to the top of the formalin jar.
3. BLS procurement will submit specimen to BLS Histology for FFPE processing. Standard fixation period of 24-72 hours. H&E and trichrome stain requested.

Core 2:

1. Prepare OCT quick freeze box by adding liquid nitrogen. This must be done after the core is collected because the liquid nitrogen vapor will dissipate quickly.
2. Take the second core out of PBS and place it in one OCT mold.
3. Ensure mold is labeled.
4. Add OCT compound into mold containing core. Ensure no bubbles surround the tissue.
5. After OCT sample is frozen, remove and transfer to -80C freezer storage.

If liver is collected as a wedge:

1. One wedge will be removed in the OR and placed in PBS.
2. Split wedge in half and treat as core 1 and core 2, processing according to same instructions.

Adipose:**Visceral:**

1. BLS will drop off PBS in specimen container at the start of the procedure.
2. Surgeon will excise 5-10 g visceral fat and place in specimen container with PBS. OR staff will page BLS for specimen pickup.
3. The location of the tissue collection will be recorded by the surgeon.
4. BLS will pick up specimen immediately and request Bionet Research Specimen Order. Short transit/processing time is critical.
5. See table below for processing priorities.
6. OCT and FF samples will be stored at -80C until pick up.
7. Fresh in media samples will be stored at 4C until pick up.
8. BLS procurement will submit formalin specimens to BLS Histology for FFPE processing. Standard fixation period of 24-72 hours. H&E requested.

Sample number	FFPE	OCT	Flash Frozen	Fresh in Media
1	1g			
2		1g		
3			1g	
4				2g
5	1g			
6		1g		
7			1g	
8				Remainder

Subcutaneous:

1. BLS will drop off PBS in specimen container prior to procedure.
2. Surgeon will excise 5 g subcutaneous fat and place in specimen container with PBS. OR staff will page BLS for specimen pickup.
3. The location of the tissue collection will be recorded by the surgeon.
4. BLS will pick up specimen immediately and request Bionet Research Specimen Order. Short transit/processing time is critical.
5. See table below for processing priorities.
6. OCT and FF samples will be stored at -80C until pick up.
7. Fresh in media samples will be stored at 4C until pick up.
8. BLS procurement will submit formalin specimens to BLS Histology for FFPE processing. Standard fixation period of 24-72 hours. H&E requested.

Sample number	FFPE	OCT	Flash Frozen	Fresh in Media
1	1g			
2		1g		
3			1g	
4				1g
5	Remainder			

Blood:

1. Study team will set up blood processing instructions with TTL.
2. Study team will place order for blood in EPIC. Please provide BLS pager number 612-899-5734 in the order notes for pickup contact.
3. Study team will provide preop staff with blood tube collection kits. 2 x 10 mL EDTA blood tubes will be in a bag labeled with BLS pager number for pick up contact.
4. Blood tubes will be held at room temperature until delivery to TTL or pick up by study team.
5. BLS will pick up blood tubes and submit to TTL for processing.
If filled blood tubes are returned to BLS past TTL's 2pm processing deadline, study team will be notified to pick up blood tubes and process through Laura Niederhofer's lab.

5. **Specimen Release:** BioNet will email the research team when specimens are ready for pick-up. Specimens can be picked-up at the BioNet office (Mayo C338) before 4:00PM. Signature confirmation of receipt will be required.
 1. BLS will email study team for pickup ASAP since immediate pickup of fresh samples is ideal. Study team will pick up samples after 2pm.
 2. Study team will pick up fresh, OCT, and snap frozen samples the same day.
 3. If BLS was unable to submit blood to TTL, study team will pick up blood the same day.
 4. Study team will pick up FFPE blocks when they are ready (~1-2 weeks after procedure day).
6. **Follow-Up:** If collection containers or media are stored with BioNet, the researcher will provide new ones for future collections when needed.

Other Notes:

- If study protocol or personnel change, please contact bionet@umn.edu to amend the Procurement Agreement.

Agreement for Use of Specimens:

The Principal Investigator agrees that specimens provided by BLS will be used for research purposes only. Specimens and their products shall not be sold or used for commercial purposes, nor will specimens be distributed further to third parties for purposes of sale, or producing for sale, cells, or cell products. The specimens are provided as a service to the research community without warranty or merchantability of fitness for a particular purpose or any other warranty, expressed or implied.


Liability Agreement:

The Principal Investigator understands that although BLS attempts to avoid supplying specimens contaminated with highly infectious agents, all specimens should be handled as if potentially infectious. BLS accepts no responsibility for any injury (including death), damage, or loss that may arise either directly or indirectly from their use. The Principal Investigator assumes all risks and responsibility in connection with the receipt, handling, storage, and use of specimens. The Principal Investigator also assumes full responsibility for informing and training all personnel in the danger and procedures for safe handling of these and all other human tissues. The Principal Investigator further agrees to indemnify and hold harmless BLS and the University of Minnesota for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the specimens provided by BLS.

BLS Procurement Team Contacts:

Bobby Gillespie	gille610@umn.edu
Caitlynn Olson	olso9051@umn.edu
Emily Hignell	higne002@umn.edu
Paari Murugan	pmurugan@umn.edu
Rachel Floersch	floer013@umn.edu
Jenny Pham	pham0435@umn.edu

BioNet Office (Mayo C338):	612-273-6680
Day Pager:	612-899-5734
After-Hours Pager:	612-899-8200
BioNet General E-mail:	bionet@umn.edu


Elizabeth Thompson, PhD
Project Lead


Shannon Jannatpour
Lead Coordinator


Paari Murugan, MD
Medical Director, Biorepository & Laboratory Services



Jenny Pham, PhD
Program Director, Biorepository & Laboratory Services

Author: Jenny Pham

Date Effective: 05/05/2022

6/14/2022 DATA ADDENDUM

Study team requests BSI report within one week of each collection containing: BSI ID, date drawn, MRN, age at procedure, ethnicity, race, gender, time drawn, time processed, material type, material modifiers, vial modifiers, volume, volume unit, notes, label notes

8/30/2022 AFTERHOURS ADDENDUM

** For procedures that go into BLS after-hours the OR staff will place all samples on formalin and BLS will collect on the next business day. Samples collected (depending on consent and OR procedures) may include: 1 liver core as FFPE, 1-2 FFPE blocks of visceral fat, and 1 FFPE of subcutaneous fat.