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Revision History		
Version No.	Effective Date	Description

Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide detailed instructions and guidelines for integrating research specimen collection into routine clinical visits. This includes creating a Velos account linked to the IRB-approved protocol and requesting a custom Research Laboratory Requisition form for the study.

Scope and Responsibilities:

This SOP applies to all investigators, research staff, and personnel involved in adding a research blood draws to a clinical visit within the Department of Neurosciences at UCSD. Additionally, this SOP outlines responsibilities for ensuring compliance with research billing procedures, and processing of research samples to ensure the billing is routed to the appropriate study account.

Definitions and Acronyms:

ACTRI	Altman Clinical & Translational Research Institute
IATA	International Air Transport Association
COA	Chart of Accounts (AKA Chart String)
CRB	Clinical Research Billing
CTRI	Clinical & Translational Research Institute
EPIC	EPIC (Electronic Medical Records system)
ICF	Informed Consent Form
IRB	Institutional Review Board
PI	Principal Investigator
TRT	Translational Research Technology
UCSDH	University of California, San Diego Health
Velos	System for clinical trial management & research billing

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Process:

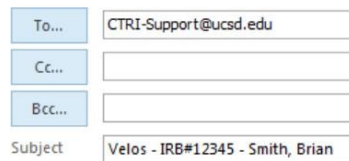
1. Pre-Velos Account Creation:

Initiate a Research Account Application in Velos. The Velos account, ensures the research study is linked to the IRB-approved protocol for sample collection in the biobank. Velos interfaces with EPIC overnight, allowing for billing of research charges to the proper study account - Chart String (COA) - .

1.1 Email CTRI support ctri-support@ucsd.edu the following documents:

- IRB number
- Proposed study name or acronym for easy identification
- Attach a copy of the consent
- Attach a copy of the research plan or protocol
- In the subject line add the following in this exact format:

“Velos-IRB Number-PI Last Name, First Name”



The image shows a screenshot of an email composition interface. It features four input fields: 'To...' with the value 'CTRI-Support@ucsd.edu', 'Cc...' which is empty, 'Bcc...' which is empty, and 'Subject' with the value 'Velos - IRB#12345 - Smith, Brian'.

1.2 The study team will receive an email acknowledging the request was received. The Velos Team will process the request within 24-48 hours.

2 Post-Velos Account Creation

2.1 After the Velos Account is created, the study team must complete applicable Velos forms for biobanking, including the Research Account Form and Research Laboratory Form. Ensure that the financial Chart String is correctly entered in the Research Account Form, as this is needed for Clinical Research Billing (CRB) to generate the Research Account Number and to link it with EPIC for proper billing.

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Field Name	Field Length	Field Type
Financial Unit	7	Numeric
Fund	5	Alpha/Numeric
PPM Expenditure Type	6	Numeric
Function	3	Numeric
PPM Project	7	Numeric
PPM Task	3	Numeric

2.2 After the Research Account Number is created, the Laboratory Systems Team will issue an email notifying the study team the account is finalized, Example of notification with Research Account Number on far-right column. This number is needed to request the research custom laboratory requisition form, also called the “pink form”.

IRB #	Study Coordinator	Phone #	E-Mail Address	Type of Application	Research Account #
809909	Jane Smith	858-657-7107	example@health.ucsd.edu	New	32348826

3 Custom Research Laboratory Requisition Form Request

- 3.1 Request a study specific laboratory requisition form by emailing Laboratory Administration: Carlo Martinez at ctmartinez@health.ucsd.edu.
- 3.2 Note that the “Lab Requisition Form” can only be requested after the Velos Account is created and the Research Account Number is issued.
- 3.3 Carlo will send a study-specific questionnaire for completion, after which the custom lab requisition form will be created (Appendix A).
- 3.4 Carlo will provide the study staff the links to view the study form and to request copies from the UCSDDH Copy Center. This process takes approximately 2 days.

Copy Center Order link:

<https://secure-web1.ucsd.edu/formOrder/formlogin.aspx>

D-Form **D4773** Draw Form image link:

<https://pulse.ucsd.edu/departments/supplychain/Documents/formDocs/D4773.pdf>

- 3.5 The custom laboratory requisition form must be renewed annually.

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4 Informed Consent within Clinical Appointments

- 4.1 The assigned coordinator or physician will complete the informed consent process while the participant is in the exam room or immediately after the visit, provided that a private space available for ICF discussion. It is preferable to obtain consent before or during the clinic visit to guarantee participant enrollment.
- 4.2 A copy of the ICF should be provided to the participant and the original should be filed in the participant’s chart or study binder.

5 Completing the “Pink Form” and Research Sample Draw

- 5.1 The physician will order the clinical labs as usual through the EPIC system.
- 5.2 The PI, or any member of the study team will fill out the "custom laboratory requisition/pink form" with the participant’s details (name, Subject ID, MRN, etc.). The study-specific details are prefilled.
- 5.3 Study staff and/or participant proceed to the lab for their blood draws. Alternatively, the participant can proceed to the lab by themselves and provide the “pink form” to the laboratory staff.
- 5.4 The cost of a research lab draw, regardless of number of tubes is \$8.83
- 5.5 The laboratory locations closest to UCSD East Campus clinic locations are as follows. These locations do not require appointments.

Perlman Medical Offices

9350 Campus Point Drive
San Diego, CA 92037
858-657-8690
Monday-Friday: 7:30 a.m. - 6 p.m.
**Last patient check-in at 5:30 p.m.*

8910 Villa La Jolla Drive

San Diego, CA 92037
858-657-7000
Monday-Friday: 7 a.m. - 8 p.m.
**Last patient check-in at 7:30 p.m.*
Saturday-Sunday: 8 a.m. - 12 p.m.]

4510 Executive Drive

4510 Executive Drive, Suite 327
San Diego, CA 92121
858-657-7498
Monday-Friday: 8 a.m. - 12:30 p.m. and 1 - 4:30 p.m.
(Closed for lunch: 12:30-1 p.m.)

- 5.6 Study staff must provide properly labeled (MRN, name of subject) collection tubes to the laboratory in a biohazard bag.

6 Post-Draw and Processing of Samples

- 6.1 The study team is responsible for retrieving the samples after the draw.

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6.2 The study team is responsible for updating the Velos system within 5-7 days of the service date to avoid billing issues (e.g. participants inadvertently billed for research-related blood draws).

6.3 There are two options for sample processing:

6.3.1 Option 1: A properly trained study coordinator (IATA certified) retrieves, processes, labels and stores the samples in a PI designated freezer. Processed samples can also be stored at the ACTRI TRT freezers by establishing an account for storage purposes only.

6.3.2 Option 2: An account is set up with ACTRI TRT. The study coordinator retrieves the samples from the clinical lab and delivers them to the TRT for processing, labeling, and storage.

6.4 Consultation requests for a biorepository account can be made through the ACTRI TRT Service Request Form: [ACTRI TRT Services Request Form \(jotform.com\)](http://jotform.com).

6.5 TRT Recharge fee sheet is included in Appendix A. Additional fees may be incurred for sample retrieval, shipping, etc.

6.5.1 Processing and Storage Costs Details:

Processing Time and Costs:

- **Time to Process:** 40 cryovials takes approximately 1 hour.
 - **Processing Cost by a SRAI:** \$85 per hour.
 - **Processing Cost by a SRAII:** \$110 per hour.
- **Material Costs:** included if TRT processes and aliquots samples. Otherwise, there is a charge of \$0.08/each for thermal labels.
- **Additional costs:** there is an additional charge if TRT provides collection tubes.

Storage Fees:

- **Cost Per 2” or 3”Box:** \$27 per box per month.
- **Box Capacity:** 2” box can hold up to 81-1.5 ml cryovials (approximately two sets of 40 samples). 3” are for whole blood storage and holds 6 ml size tubes and 36-1.5 cryovials.

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- **Rack Storage Rate:** After 6 boxes, storage moves to a rack system.
 - **Rack Rate:** \$164 per rack per month.
 - **Rack Capacity:** Each rack holds up to 24 boxes.
 - **Example 1:** For 18 boxes, the cost is \$164 (full rack rate).
 - **Example 2:** For 27 boxes, the cost is \$164, which includes \$164 for the full rack (24 boxes) and an additional \$81 for the extra 3 boxes.

5 Documentation

All forms and records, including the custom lab requisition forms, TRT drop off form and signed Informed Consent Forms, must be filed in the participant's research binder. Any changes to the study protocol must be reflected in updated IRB amendments and updated ICFs and HIPAA forms if applicable.

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Appendix A:

Custom Research Lab Requisition Form (AKA **Pink** Form)

UC San Diego Health

RESEARCH REQUEST FOR PHLEB PROCESSING

Hillcrest Blood Drawing Room: 619.543.6665
 Thomson Bio: 1.657.8690
 Moores Canc: ng Room: 858.822.6145

BLOOD DRAW
SOFT TEST : PHLEB

PROCESSING
SOFT TEST : HNCHO

BULK ACCOUNT USE ONLY

Date: _____ Medical Record: _____
 Name: _____
 CBN/Subject ID: _____
 DIAGNOSIS (REQUIRED): _____
 Study Name: **ROPAD ROSTOCK INT PD**
 Bulk#: **9902199** Expires: **05.16.21**

Ordering: _____

ROPAD					
Location	Drawn By	Tube Count	Yes	No	Urine

IRB 200397 RESEARCH DRAW APPROVED

VALID ONLY for RESEARCH TUBE DRAW

Draw as extra tubes off Standard of Care (SOC) or
 if no SOC order from physician then create separate order for
 Research Draw Only - **PHLEB** applies

1. Study Coordinator will accompany patient with consent for draw
2. Enter Extra tubes on SOC order or create new order with PHLEB if no Standard of Care
3. Draw using labeled tubes supplied by Study Coordinator
4. Label and date/time (if label is supplied by study - write Date/Time of draw on label)
5. Enter tube count on this form and urine (if obtained)
6. Forward tubes for tests specified on SOC order to Processing (if SOC ordered)
7. Place tubes into Biohazard bag and hold at room temperature until 4:00 PM or until released.
8. Obtain Biohazard Release (below) and validate badge before releasing specimen(s)

Research Coordinator: _____

BIOHAZARD RELEASE - COMPLETION REQUIRED

☛ This blood, drawn for research purposes, is obtained in accordance with an IRB approved research protocol.
 ☛ My signature certifies receipt of human blood and/or urine (in biohazard labeled container) to be transported in compliance with UC San Diego Health biohazard materials safety protocols.

Date _____ Time _____ Badge No _____ (list 5 digits)
 Printed Name _____ Signature _____

Processing Instructions and Approvals: [www.pw-emerged-with-UCSDH-Clinical-Laboratories](#) - email: clm@ucsd.edu
 D4773 ROPAD (9-20)

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Appendix B:

RECHARGE RATES – Translational Research Technology Center (TRT) Laboratory

As of 7/1/2024

<p><i>Campus units that receive part of or their entire operating budget from recharge income are required to establish recharge rates in accordance with applicable University and federal policies. As part of the annual budget process, recharge units are required to submit for review and approval information regarding their projected costs and recharge rates for the upcoming year.</i></p>	<p>Service requests must come through the ACTRI website request form in order to receive the approved recharge rates. Link here: https://ucsd-actri.iotform.com/232777038956874</p>
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TRT Laboratory

Lab Services Questions | David Boyle dboyle@ucsd.edu

Storage and Shipping

SERVICE	DETAILS	UNIT	UC Users
Freezer Box	2-inch box	MONTHLY	\$27
Freezer Box	3-inch box	MONTHLY	\$59
Freezer Rack (per 12-24 boxes)		MONTHLY	\$164
Liquid Nitrogen Rack		MONTHLY	\$109
Storage Retrieval		per ACCESS	\$65
Sample Pulling		HOURLY	\$85
Sample Shipping	Labor	HOURLY	\$85
Sample Shipping	FedEx	VARIABLE based on actual shipping costs	Pass through
Sample Shipping	Dry Ice Charge	Per SHIPMENT	Pass through
Sample Shipping	Miscellaneous Costs	VARIABLE based on actual shipping costs	Pass through

Assays

SERVICE		UNIT	UC Users
DNA Extraction Blood/Cells	for 1-12 Extractions (Includes labor time, kit costs)	per SAMPLE	\$99
	for 13+ Extractions	per SAMPLE	\$54
DNA Extraction Tissue	for 1-12 Extractions	per SAMPLE	\$144
	for 13+ Extractions	per SAMPLE	\$72
RNA Extraction Blood	for 1-12 Extractions	per SAMPLE	\$101
	for 13+ Extractions	per SAMPLE	\$56
RNA Extraction Cells	for 1-12 Extractions	per SAMPLE	\$101
	for 13+ Extractions	per SAMPLE	\$56
RNA Extraction Tissue		per SAMPLE	\$160
PCR—Qpcr—DNA		per REPLICATE	\$33
SRA I Labor and Consult	SRA I Tech Time if not already included in testing	HOURLY	\$85
SRA II Labor and Consult	SRA II Tech Time if not already included in testing	HOURLY	\$110
Sr. Faculty Consult		HOURLY	\$161

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Document Approval

- Document Approval me and Title of Approver
- Date in the format (MM/DD/YYYY)
- Insert Name and Title below Signature

Approved By:

Date:

Insert Name and Title