

Clinical Lab Services for Research Studies



Overview:

This document describes the process for working with the Stanford Clinical Lab group when lab processing is required as part of a clinical research study conducted through Stanford Children's Health (SCH) or Stanford Health Care (SHC). For questions or to suggest additional content, please contact the Clinical Research Support Office (CRSO) at crso@stanfordchildrens.org

Table of Contents:

Section I: Request a Feasibility Assessment

Section II: Submit the 'Request for Clinical Lab Requisition Form'

Section III: Obtain the Lab Requisition Form

Section IV: Conduct the Study with Clinical Labs

Section V: Study Renewals

Section VI: Close the Study with Clinical Labs

Appendix

I. Request a Feasibility Assessment for Research Studies with Clinical Labs

WHY:

To determine if Clinical Labs can support your study.

As a general guidance, a feasibility assessment is required **except when:**

- All study labs are routine and/or available on the dropdown menu of the budgeting/billing workbook (Ex: CBC, MetC, Urinalysis)

If you are still not sure if a feasibility assessment is required, please contact Clinical Labs ([Ester Bengil](#) & [Kristine Ubungen](#)) via email. You can also contact the Clinical Research Support Office (CRSO) for assistance.

WHEN:

Prior to submitting the study workbook to Research Management Group (RMG) (http://med.stanford.edu/spectrum/b1_researcher_resources/b1_2_forms_templates.html), you should request a feasibility assessment from Clinical Labs to ensure that they can meet the laboratory needs of the study. If you expect the study start-up process to take more than 3 months, please be sure to let Clinical Labs know.

HOW: Complete the following step:

1. Initiate an e-mail communication with Clinical Labs (Ester Bengil & Kristine Ubungen).

The subject line of the e-mail should be: “eProtocol xxxxx: Study Feasibility”

In your e-mail, **include:**



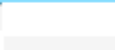

- **Section of Lab Manual that contains lab collection, processing and shipping instructions (not the whole manual).**

This should include tube types, temperature requirements for storage and transport, maximum time to process or ship, centrifuge instructions, etc.

Example:

Specimen Collection Procedures

PLASMA

TESTS	VISITS	COLLECT	RETURN	
PLASMA BIOMARKER	Screening Day		2 mL 	FROZEN -70°C OR LOWER WEEKLY
	Study Treatment Discontinuation	1 x 1 mL lavender top EDTA tube	1 x cryovial	TO: 
<ol style="list-style-type: none"> 1. Check the tube expiry date. Do not use expired tubes. 2. Label all tubes with the subject's identification (screening and/or patient ID, where applicable). 3. Draw 1 mL of blood into lavender top vacutainer tube using standard venipuncture techniques. 4. Invert the tube gently 8-10 times. One complete inversion is to turn the filled tube upside-down and return it to upright position. Note: Do not shake. Inadequate mixing may result in platelet clumping, clotting and/or incorrect test results. 5. Store on wet ice until centrifugation 6. Centrifuge for 10 minutes, 1500xg, 4°C, within 30 minutes of blood collection. 7. Transfer all the plasma into each appropriately labeled cryovial. 8. Freeze at -70°C or lower and store samples upright until shipment. If a -70°C freezer is not available, the sample may be stored at -20°C for a week and shipped to  weekly. 9. If freezing at -70°C or lower is possible, batch ship sample weekly on dry ice to Covance CLS. 10. Ad-hoc shipments may be requested by the Sponsor. 				

If Clinical Labs has questions regarding the study labs and the CRC cannot answer these questions, the CRC will need to reach out to the Sponsor to provide clarification. Clinical Labs personnel do not contact Sponsors/monitors.

- **Whether or not your study may require after hours or weekend sample processing.**

After hours processing requires notifications and additional documentation.

Clinical Labs will respond to the feasibility assessment by e-mail within 2 weeks and indicate if study is feasible and, if so, whether or not after hours/weekend processing will be available. Please note: Clinical Labs can only store research samples up to 3 months.

II. Submit the 'Request for Clinical Lab Requisition Form'

WHY:

A completed 'Request for Clinical Lab Requisition Form' is required by Clinical Labs in order to create a Clinical Lab Requisition Form. The Clinical Lab Requisition Form allows Clinical Labs to collect and process research samples and charge them appropriately. This ensures that patients are not charged for study-related activities. **DO NOT create your own requisition form!**

WHEN:

The 'Request for Clinical Lab Requisition Form' should be submitted to Clinical Labs as soon as all of the following items are obtained and before the first patient is enrolled:

- IRB approval letter
- Finalized Budget/Billing workbook including active hospital account number (see **HOW** section below)
- Executed contract (where applicable)

HOW: Complete the following step:

1. Initiate an e-mail communication with Clinical Labs (Ester Bengil & Kristine Ubungen).

The subject line of the e-mail should be: "eProtocol xxxxx: New Study Submission"

In your e-mail, **include:**

- **Complete the 'Request for Clinical Lab Requisition Form'** - click [here](#) to obtain the form. The Request for Clinical Lab Requisition Form requires an active hospital account number or account name
 - To obtain an account name or account number, you must submit the final workbook to Patient Financial Services (PFS) for their approval. Once approved, PFS will provide the account name/account number. PFS will require a PTA#. Workbook templates and other instructions can be found by [here](#) (Under Study Team Resources: Budget & Billing)
 - All studies require a workbook be submitted to PFS, even "No bill" studies or those using discarded specimens from routine labs.

Example of the 'Request for Clinical Lab Requisition Form':

Stanford HEALTH CARE
STANFORD MEDICINE

All frozen specimens will be held for 3 months with Ester Bengil, (650) 498-8023. After 3 months, a phone call will be made to the Study Coordinator and/or PI to see if the specimens is still needed. If I do not hear from you within a week after the call, the specimens will be frozen.
I have read and agree to the above statement.

REQUEST FOR CLINICAL LAB REQUISITION FORM

Please include a copy of the IRB Letter of Approval and any special instructions, specimen requirements, and/or send-out instructions upon submission of this form.

Today's Date: _____
Study Name: _____

Stanford Project Director/Investigator/Physician's Name: _____
Primary Diagnosis Code (Example: Z00.00): _____
Dept. Name: _____
Contact Person: _____ Phone #: _____
Start Date and Duration of Study: From _____ TO _____
Frequency of Specimens: _____
Who Will Collect the Specimens: _____
Number of Patients in Study: _____
Are they Inpatients or Outpatients: _____
Account Number: _____
(Is this to be billed to the Patient, an 80098 number, or mnemonic account?)
Will the Laboratory be doing the Testing? _____
If so, please specify which tests you are requesting: _____

If not, at which lab will tests be done? _____
Should the patient's medical record number appear on the report? Should it be Identified or de-Identified?
If not what code name(s) will you be using? _____
Mail Results To: (Please provide name and mailing address for where printed results will be sent) _____

PLEASE RETURN THIS FORM TO: Ester Bengil - (FAX) 650-723-6752, email: ebengil@stanfordhealthcare.org
Stanford Health Care and Stanford Children's Health, Clinical Laboratories, 300 Pasteur Dr., MIC 3627, Stanford, CA 94305

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- IRB approval Letter
- Section of Final Lab Manual that contains specimen collection, processing and shipping instructions (not the whole manual)
 - If there have been any changes to the specimen collection, processing or shipping instructions since the feasibility assessment, please indicate what those changes are.
 - Please do not send the entire lab manual to Clinical Labs
- Copy of all feasibility assessment e-mail communications with Clinical Labs.

Clinical Labs may initiate a meeting with the CRC if required. **Approval takes approximately 2 weeks.**

III. Obtain the Lab Requisition Form

WHY:

The Lab Requisition Form will be used as an order for Clinical Labs to collect and/or process the samples. Clinical Labs cannot draw and/or collect, accept, or process research samples without the lab requisition form.

WHEN:

Before enrolling first patient.

HOW:

Once Step II (above) is completed, lab personnel will create the Lab Requisition Form and provide an electronic version to the CRC. Enrollment can then begin.

IV. Conduct the Study with Clinical Labs

WHY:

To ensure that all study visits run smoothly and Clinical Labs has everything they need to process and collect samples in a timely manner.

WHEN:

When study is open to enrollment.

HOW:

Complete the following steps for **each patient visit**:

1. Complete the Lab Requisition Form and notify Clinical Labs at least 24 hours prior to the study visit.
 - a. This requisition should accompany the specimens. Clinical Labs requires the paper requisition form for each sample processing, even if orders have also been placed in EPIC.
2. Provide pre-labeled tubes and shipping materials for each patient visit.
 - a. ***Please note the lab does not provide any study supplies.***
3. Provide a copy of the specific processing instructions for each particular visit, not the entire laboratory manual.
4. If your visit is taking place outside the Clinical Lab usual business hours of 7:30am to 6:00pm Monday through Friday or on the weekends, provide items above to Clinical Labs in advance of the visit, and include information about the anticipated collection time(s).

V. Study Renewals

Lab Requisition Forms expire after one year and need to be renewed annually along with the IRB approval letter. Please note that some minimal risk studies may not have an IRB expiration date or may be approved by the IRB for a period longer than 3 years. These studies still require annual renewal with Clinical Labs even if IRB renewal is not required annually. Complete the following step **within one week after IRB approval of continuing review**:

1. Initiate an e-mail communication with Clinical Labs (Ester Bengil & Kristine Ubungen).

The subject line of the e-mail should be: *"eProtocol xxxxx: IRB Annual Renewal"*

In your e-mail, **include:**

- IRB annual renewal approval letter
- Expired lab requisition form

Clinical Labs will then update the Lab Requisition Form within 2 weeks.

VI. Close the Study with Clinical Labs

WHY:

To ensure that Clinical Labs is aware they no longer need to support the study.

WHEN:

The study team should notify Clinical Labs that the study is closing when their services are no longer required.

HOW:

Complete the following steps:

1. Email Clinical Labs (Ester Bengil and Kristine Ubungen) to inform them no further lab services will be required for the study. The subject line of the e-mail should be: *"eProtocol xxxxx: Study Closeout"*
2. If you have frozen samples, please set up an appointment with Clinical Labs to coordinate shipping the samples. Clinical Labs needs at least 24 hours' notice to ship any samples. Clinical Labs can store research samples up to 3 months.

Appendix

Clinical Labs Locations and Hours

- Clinical Labs: Monday – Friday: 7:30am – 5 pm
- SCH (Pediatrics):
730 Welch – Mary Johnson Building (M-F 7:30 am – 5:30 pm – no holidays)
725 Welch – LPCH Main (M-F 7:00 am – 5:30 pm; Saturday: 8:00 am – 4:30 pm, with 24 hours dispatch available)
- SHC (Adults):
Blake Wilbur (M-F 7:30 am – 5:30 pm – no holidays)
300 Pasteur Drive – Stanford Hospital – A101- Ambulatory clinic (M-F 7:30 am – 5:30 pm;
Saturday: 6 am – 3:30 pm – (no holidays)

Do not drop off samples with Clinical Labs.

Contact Information

Clinical Labs:

- Ester Bengil: EBengil@stanfordhealthcare.org
- Kristine Ubungen: kubungen@stanfordhealthcare.org

When sending e-mails to Clinical Labs, please send the e-mail to *both* Ester Bengil and Kristine Ubungen

Send-Out Labs: (650) 725-5623

Clinical Research Support Office (CRSO):

- crso@stanfordchildrens.org
- Alyson Falwell
Clinical Research Operations Manager
Stanford Children’s Health
Phone: (650) 304-7118
AFalwell@stanfordchildrens.org

Patient Financial Services (PFS):

- SHC : Jacqueline Barajas @ JBarajas@stanfordhealthcare.org
- SCH: Sydney Piaia @ SPiaia@stanfordchildrens.org
This team processes study financial workbooks to generate account numbers used in the Lab Requisition forms.

Leftover Samples

For access to discarded leftover samples from routine clinical labs, please contact Clinical Labs (Ester Bengil & Kristine Ubungen) via email. In order to access leftover clinical samples for research, the research study must be set up with Clinical Labs by following the standard set up process.

Other: Forms and Policy Updates

- [Clinical Laboratory Documentation Request](#) (Under Study Team Resources: Forms: Request & Requisitions / Lab Forms)
- [New Clinical Laboratory Policy - Pediatric maximum blood draw volumes for clinical trials \(5/24/19\)](#)

Acronyms and Definitions

SCH	Stanford Children's Health
LPCH	Lucile Packard Children's Hospital
SHC	Stanford Health Care
CRC	Clinical Research Coordinator
CRSO	Clinical Research Support Office
PFS	Patient Financial Services
PTA	Project Task Award
RMG	Research Management Group