

Clinical Lab Services for Research Studies



Overview:

This document describes the process for working with Special Studies in Clinical Labs for research studies 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 from Special Studies in Clinical Labs

WHY:

To determine if Special Studies in 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 Special Studies (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 Special Studies 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 Special Studies know.

HOW: Complete the following step:

- 1. Initiate an e-mail communication with Special Studies** (Ester Bengil & Kristine Ubungen). The subject line of the e-mail should be: *“eProtocol xxxxx: Study Feasibility”*
In your e-mail, **include:**

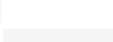
- Section of Lab Manual that contains lab collection, processing and shipping instructions (not the whole manual)

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 Special Studies has questions regarding the study labs, the CRC needs to reach out to the Sponsor to provide clarification. Please do not provide the Special Studies contact information to Sponsors/monitors.

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

After hours processing requires notifications and additional documentation.

Special Studies 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 Special Studies 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 Special Studies in order to create a Clinical Lab Requisition Form. The Clinical Lab Requisition Form allows Special Studies 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 Special Studies as soon as all of the following items are complete (before the first patient is enrolled):

- After the IRB approves the study
- After the billing workbook is finalized with PFS (see **HOW** section below)
- After the contract is executed (for industry studies)

HOW: Complete the following step:

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

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

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

- **Completed the ‘Request for Clinical Lab Requisition Form’** - click here to obtain the form

The Request for Clinical Lab Requisition Form requires an account number or account name (for SHC/adult participants, the account number should start with 98; for SCH/pediatric subjects, the account name is a client mnemonic)

- To obtain an account name or account number, you must submit the final workbooks 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 [here](#)
- All studies require a workbook by the lab and by patient financial services, even “No bill” studies or those using discarded specimens from routine labs.

- **IRB approval Letter**

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

Example:



All frozen specimens will be held for 3 months with Ester Bengli, (650) 498-5923. After 3 months, a phone call will be made to the Study Coordinator and/or PI to see if the specimens are still needed. If I do not hear from you within a week after the call, the specimens will be tossed.

I have read and agree to the above statement: _____

CLINICAL LABS - STUDY PROTOCOL 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: _____

Project Director/Physician's Name: _____

Primary Diagnosis Code (Example: Z30.00): _____

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 80088 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 name and/or medical record number appear on the report? _____

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 Bengli - (FAX) 650-723-4752; email: ebengli@stanfordhealthcare.org
Stanford Health Care and Stanford Children's Health, Clinical Laboratories, 300 Pasteur Dr., M/C 5627, Stanford, CA 94305

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 Special Studies

- **Copy of all feasibility assessment e-mail communications with Special Studies.**

Special Studies may initiate a meeting with the Clinical Research Coordinator 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 Special Studies to collect and/or process the samples. Special Studies 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.

Left Over Samples

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

IV. Conduct the Study with Special Studies in Clinical Labs

WHY:

To ensure that all study visits run smoothly and Special Studies 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 prior to the study visit.
 - a. This requisition should accompany the specimens. Special Studies require the paper requisition form for each sample processing, even if orders have also been placed in EPIC.
2. Provide and pre-label all 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 lab hours of 7:30am—6:00pm Monday through Friday or on the weekends, provide items above to Special Studies in Clinical Labs in advance of the visit, and be sure to include information about the anticipated collection time(s).

V. Study Renewals

Lab Requisition Forms expires after one year and need to be renewed annually along with the IRB. Complete the following step within one week after IRB approval of continuing review:

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

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

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

- Copy of the IRB annual renewal approval letter
- Copy of expired lab requisition form

Special Studies will then update the Lab Requisition Form within 2 weeks.

VI. Close the Study with Special Studies in Clinical Labs

WHY:

To ensure that Special Studies is aware they no longer need to support the study.

WHEN:

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

HOW:

Complete the following steps:

1. E-mail Special Studies (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 Special Studies in 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

- Special Studies in Clinical Labs: Monday – Friday: 7:30am – 5 pm
- 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 hour dispatch available)

2019-08-28-19

- **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 Special Studies in Clinical Labs.

Contact Information

Special Studies in 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.

Other: Forms and Policy Updates

- [Clinical Laboratory Documentation Request](#) (Under Forms: Request & Requisitions)
- [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

2019-08-28-19

CRC	Clinical Research Coordinator
CRSO	Clinical Research Support Office
PFS	Patient Financial Services
PTA	Project Task Award
RMG	Research Management Group