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

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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**

<table>
<thead>
<tr>
<th>TESTS</th>
<th>VISITS</th>
<th>COLLECT</th>
<th>RETURN</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLASMA BIOMARKER</td>
<td>Screening Day</td>
<td>1 x 1 mL lavender top EDTA tube</td>
<td>[FROZEN -70°C OR LOWER WEEKLY]</td>
</tr>
<tr>
<td></td>
<td>Study Treatment Discontinuation</td>
<td></td>
<td>1 x cryovial</td>
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</tbody>
</table>

   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 in 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 xxxx: 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:

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)

- **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
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

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<th>Definition</th>
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<tr>
<td>SCH</td>
<td>Stanford Children’s Health</td>
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<tr>
<td>LPCH</td>
<td>Lucile Packard Children’s Hospital</td>
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<tr>
<td>SHC</td>
<td>Stanford Health Care</td>
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<tr>
<td>CRC</td>
<td>Clinical Research Coordinator</td>
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<td>Project Task Award</td>
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<td>RMG</td>
<td>Research Management Group</td>
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