**PURPOSE** – Study Initiation Form (SIF) for Clinical Research Specimen Processing (CRSP) provides:

1. Training reference for the clinical study team on the logistics of working with CRSP.
2. Summary of study specific information for reference by CRSP staff.
3. Necessary study and invoicing details for SR Billing.

|  |  |
| --- | --- |
| Protocol Name |  |
| Short Name |  | PI |  |
| RG# |  | Study Manager |  |
| Project/budget |  | Study Manager Mailstop |  |
| # of Subjects |  | Investigator Initiated Trial (IIT) | [ ]  Yes [ ]  No |

1. Study documents were reviewed by CRSP, and the following indicated services were found applicable.

| **Select** | **Code** | **Description** | **UOM** | **Notes** |
| --- | --- | --- | --- | --- |
| [ ]  |  | Satellite Lab for <30 min Processing |  |  |
| [ ]  |  | Satellite Lab for IMTX support |  |  |
| [ ]  | SPR10010 | Accessioning | HR |  |
| [ ]  | SPP10064 | Biopsy fixative transfer | EA |  |
| [ ]  | SPC10300 | Cell Count/Viability 1 wash, Guava | EA |  |
| [ ]  | SPP10059 | Data Entry | EA |  |
| [ ]  | SPP10073 | Extra spin/wash | EA |  |
| [ ]  | SPP10051 | Misc Materials & Services | SUM |  |
| [ ]  | SPR10008 | Monthly Storage -80 std box | EA |  |
| [ ]  | SPR10009 | Monthly Storage -80 tall box | EA |  |
| [ ]  | SPR10010 | Monthly Storage LN2 std box | EA |  |
| [ ]  | SPR10011 | Monthly Storage-FF -80 std box | EA |  |
| [ ]  | SPR10012 | Monthly Storage-FF -80 tall bx | EA |  |
| [ ]  | SPR10013 | Monthly Storage-FF LN2 std box | EA |  |
| [ ]  | SPP10065 | PAXgene | EA |  |
| [ ]  | SPP10058 | Prep and Pull from Inventory | EA |  |
| [ ]  | SPP10012 | Save Clot Serum Sep to New Tube | EA |  |
| [ ]  | SPP10053 | Shipping - Ambient | EA |  |
| [ ]  | SPP10054 | Shipping - Dry Ice | EA |  |
| [ ]  | SPP10062 | Specimen Passthru | EA |  |
| [ ]  | SPP10061 | Stool Aliquoting 1-7 vials | EA |  |
| [ ]  | SPP10032 | Swab processing | EA |  |
| [ ]  | SPP10052 | Technical Services | HR |  |
| [ ]  | SPR10014 | Additive post-collection | EA |  |
| [ ]  | SPP10060 | Additive pre-collection | EA |  |
| [ ]  | SPP10041 | Urine Measure/Aliquot 1-7 vials | EA |  |
| [ ]  | SPP10057 | WB CPT spin | EA |  |
| [ ]  | SPP10071 | WB CPT spin and aliquot | EA |  |
| [ ]  | SPP10070 | WB Ficoll, each add'l tube | EA |  |
| [ ]  | SPP10027 | WB Ficoll, first tube | EA |  |
| [ ]  | SPP10026 | WB Lyse RBC Save WBC | EA |  |
| [ ]  | SPP10021 | WB Plasma 1-7 aliquots, Lyse RBC, Save WBC | EA |  |
| [ ]  | SPP10022 | WB Plasma 8+ aliquots, Lyse RBC, Save WBC | EA |  |
| [ ]  | SPP10001 | WB Plasma/Serum 1-7 vials 1 spin | EA |  |
| [ ]  | SPP10002 | WB Plasma/Serum 8+ vials 1 spin | EA |  |
| [ ]  | SPP10013 | WB Spot/Streak, up to 2 cards/slides | EA |  |

1. **Summary of specific considerations** – Describe any special considerations supplemental to the official study documents, or any details that were clarified through communication with either the study team or sponsor. Signature on this document indicates agreement with all notes on this form that may extend the official study documents or CRSP SOPs.

[ ]  Study Team to provide processing materials “Kit” to CRSP, including:

[ ]  Tubes

[ ]  Preprinted Labels

[ ]  Shippers and waybills

[ ]  Shipping of split collections listed as shipping “Same Day” or “Day of Collection” (when part of collection is received at CRSP after cutoff for same-day shipment):

[ ]  Ship separately (ship specimens in-hand same-day, and ship late arrivals the next day).

[ ]  Hold and ship all specimens together the next day (minimizes expense).

[ ]  Quick Scans (scans of completed RSSTs emailed to contact on RSST within 2 days of processing) – incurs Data Entry service charge at 15 min increments.

[ ]  Data Entry (study-specific logs, spreadsheets, or databases) – incurs Data Entry service charge at 15 min increments. Notes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Preclarus Portal. Study Identifier in Portal: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **CRSP Contacts, Locations, and Hours** (also visit our [website](https://www.fredhutch.org/en/research/shared-resources/core-facilities/clinical-research-specimen-processing.html) under FHCC Shared Resources)

***Main Lab:*** 1208 Eastlake Ave E, T1-101, 206-667-4645

* Processing Window: Greater than 30 min
* Same-day Shipping cutoff: delivery by 1:45 pm
The Main Lab can process and package specimens received after this time, but the Study Team is responsible for taking later packages to FedEx or other service.
* Same-day Processing cutoff: delivery by 9:00 pm
Specimens arriving after this time will be processed the next business day.

***Satellite Lab*** ***(in the clinic):*** 825 Eastlake Ave E, G6-091, 206-606-6053

* Processing Window: Less than 30 min (EXCEPTION: all IMTX IIRC specimens accepted)
* Specimens must be delivered by Study Team (not FH Couriers).
* Same-day Shipping cutoff: delivery by 2:00 pm
* Same-day Processing cutoff: delivery by 3:00 pm
Specimens collected after this time must be taken to the Main Lab.

***Queries:***

* Quality Assurance Coordinator, Angela Bryce, abryce@fredhutch.org

***Pull Requests:***

* Contact processing@fredhutch.org
* Allow 2-3 weeks for scheduling.
1. **RSST Documentation** – Every scheduled collection requires advance submission of Research Specimen Scheduling Template (RSST), emailed to processing@fredhutch.org at least 48-hr prior to collection. Every effort will be made to accommodate unscheduled submissions, but priority is given to those with advance notice.

When completing the RSST, please include:

* Any special instructions not in the lab manual (e.g., third party courier pickup window).
* Contact information for on-site staff on day of collection.
1. **Kits** – All processing materials must be delivered to the appropriate CRSP lab no later than 24 hr prior to collection, but no earlier than 1 week prior to collection. Label kit supplies with
* RG#
* Subject ID / MRN
* Date of Collection
* Visit / Timepoint
1. **Portals and Third Party Applications** - CRSP’s limited staff maintain a narrow focus on “processing” in order to best serve the high volume of specimens that flow through our facility. CRSP does not support external applications or portals without prior approval and training. This includes digital pens, central lab portals, and e-requisitions. Limited exceptions to these procedures must be approved by CRSP management prior to study initiation.

EXCEPTION: The PPD Preclarus Lab Data Portal has been cleared for use by CRSP staff. Participating study teams must

* Communicate to CRSP QA at least two weeks prior to accrual.
* Confirm all CRSP staff have appropriate permissions to access the portal.
* Confirm necessary identifiers (Arm/Tx Group/etc.) are captured on each submitted RSST.
1. **Storage/Handling of pre-processed specimens** – CRSP offers a “pass-through” service for specimens which do not require processing by CRSP, yet require shipping through CRSP or storage at CRSP.
* **Specimen Pass-thru**: individual tubes must be listed on RSST.
* **Bulk Pass-thru**: a sealed box or container is delivered to the CRSP for inclusion in a shipment. The manifest and/or CSRs must be provided by the study team. The box will not be opened or individual items reviewed by CRSP.
* Accessioning (service code SPRx0010) is used for registering individual specimens, typically for storage, and invoiced per hour in 15 min increments.
* Specimen storage is billed monthly per box. A designated box is maintained in the freezer for the duration of the study unless otherwise arranged.
1. **Radioactivity** – Are radioisotopes part of subject treatment? No [ ]  Yes [ ]

Radioisotope(s) used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose administered to patient (uCi or mCi): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

List all timepoints with specimen collections post-administration, and the time interval from administration to collection: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Please note:

* No radioactive materials are handled in the CRSP Satellite Lab. All such specimens are handled in the Main Lab.
* The same-day shipping cutoff time may be earlier than for non-radioactive specimens.
* CRSP ***does not*** handle or process specimens that require shielding.

Safety Measures beyond universal precautions:

A Radiation Safety Officer (RSO) may complete these on your behalf. The RSO must review and approve these measures in the context of the primary study documents (i.e., Protocol, Lab Manual, etc.) prior to specimen collection.

[ ]  Transport to CRSP on foot in container marked “Radioactive Contents”.

[ ]  Monitor work area with: [ ]  Geiger counter [ ]  Area monitor

[ ]  Contact RSO before shipping.

[ ]  Hold specimens for 10 half-lives prior to shipping.

[ ]  Hold waste for 10 half-lives prior to disposal.

[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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RSO Signature and Date

1. **Batch Shipping Queue –** To request specimen pulls or batch shipments, email processing@fredhutch.org and include:
* RG#
* Specimen type(s) (e.g., Plasma, PBMC, Urine, etc.)
* Identifiers for requested specimens (e.g., Date of Collection, Subject IDs, etc.)
* Shipping method
* Destination
* Requested Timeframe (please provide at least two weeks notice)
* All shipping materials, including secondary containers (e.g., 95 kPa bags), shippers, and waybills, must be provided by the study team. CRSP can provide dry ice in most cases.

1. **Authorized Signatures/Dates**

Study Team signature and date

CRSP signature and date

1. **Post-Signature Addendums** (Create new PDF when an attachment is added; rename file with new date.)
2. **Revision History** (Add rows as needed.)

|  |  |
| --- | --- |
| **Effective Date** | **Revision Summary** |
|  |  |
|  |  |