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| **Title:** | **Submitting an RSST to the SPL – A Guide for Research Study Teams**  |
| **SOP #:** | SP-300-6-v01 |
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**REVISION HISTORY**

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| **Version** | **Description** | **Revised**  | **Effective**  |
| 1 | Initial Version  |  | 01Jun2023 |

**PURPOSE**

This document describes how to complete a Research Specimen Schedule Template (RSST) and submit it to the Specimen Processing Lab (SPL).

**SCOPE**

The RSST is required of all research study specimens processed at the SPL. The RSST captures all relevant identifiers and must be submitted to the SPL 48 hr in advance of the scheduled research collection. Research Study Teams should follow this guidance to ensure timely and complete capture of all requisite specimen information. During processing, the SPL updates each RSST with real time processing/handling conditions, and is eventually routed back to the Study Team. This document is specific to RSST version 5.

SPL has two locations, and each accepts specimens as follows:

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|   | ***Address*** | ***Latest Drop*** | ***Processing Window*** |
| ***Main Lab*** | 1208 Eastlake Ave E, T1-101 | 9 pm | > 30 min  |
| ***Satellite Lab (IMTX\*)*** | 825 Eastlake Ave E, G6-091 | 3 pm | < 30 min |

* “<30 min” processing is only offered at the Satellite Lab, and specimens must be delivered by 3 pm.
“<30 min” specimens not deliverable by 3 pm must go to the Main Lab (along with all associated shippers, labels, waybills, etc.) where they will be processed in the order received. The Main Lab is not responsible for delays in processing of “<30 min” specimens.
* Collection Kits that include “<30 min” specimens alongside “>30 min” specimens must be split\* for separate delivery (and separate processing) between the Satellite Lab and the Main Lab. This applies to all associated shippers, labels, etc. All specimens delivered after 3 pm, must be processed in the Main Lab.

\* IMTX study specimens deliverable by 3 pm are processed at the Satellite Lab (G6-091), regardless of processing window. “IMTX” should be appended to the RG field when completing the RSST.

**PROCEDURE**

Prior to collection, arrange delivery to the SPL of all materials necessary for processing and shipping (e.g., study kits, shippers, airway bills, cryovials, reagents, etc.). The SPL is not responsible for delays due to missing materials.

1. Access the RSST from Knowledge Hub or CenterNet. Save a copy of the RSST to your local computer (filename format “RSST\_RGCODE\_PARTICIPANTID\_VISITDATE”)
2. Complete all RSST fields shaded in blue (those pertaining to the collection).
	1. ***RG***: number assigned to a study via OnCore Clinical Trial Management System (CTMS) (i.e., RG1234567).
	2. ***Study Secondary ID***: In OnCore, see Short Title, e.g., “COVID study”
	3. ***Collection Date/Time***: Enter the \*scheduled\* date/time; actual collection date/time is reconciled later.
	4. ***Form Completed By/Date***: who completed this form / date completed
	5. Patient Identifiers – the third identifier is optional unless the subject has been de-identified:
		1. ***Subject Initials***: (First-Middle-Last)
		2. ***MRN***: medical record number (“U number”)
		3. ***Study Subject ID***: identifier assigned by the Research Study sponsor (may also be a Screen ID if a Subject ID has not yet been assigned)
	6. ***Patient Sequence #***: Optional
	7. ***Visit ID***: Collection visit name, e.g., “Cycle 1 Day 1”
	8. ***Timepoint***: Designated by Sponsor, for example, “Pre”, “Post”, “EOI” (End of Infusion), “1hr post”, “2hr post”, “EOT” (End of Treatment), etc.
	9. ***Multiple Timepoints***: Yes/No (e.g., does this form capture a “pre” and a “post” timepoint?)
	10. ***Primary Coordinator***: email, phone
	11. ***Collection Location***: Select
	12. ***Delivery Location***: Select (Satellite Lab only accepts < 3pm, **and** must be either <30 min **or** IMTX)
	13. ***30 Minute Sample***: Only check if urgent processing (<30 min) is required per Study Lab Manual.
	14. ***Most current version of Lab Manual is present in CTMS***: Please only mark Yes if the lab manual is in CTMS ***and*** it is the current version.
	15. For each test being conducted, complete the following
		1. ***Test Name***: (i.e., Chemistry, PK, etc. If sample has multiple test names, list one.)
		2. ***Bio Specimen Type***: Select
		3. ***Process Window***: Select min after collection for required processing, as per Study Lab Manual.
	16. ***Has Study Staff transported processing and shipping material to SPL***: Mark either “Yes” or “N/A”
	17. ***Special Processing/Aliquoting Instructions***: (p2, optional) details specific to a visit / test / biospecimen, shipping instruction, if the sample has a processing window not described by drop-down options, etc.
	18. ***Study Team Backups***: (p3, optional)
3. Research Study personnel submit the completed RSST to SPL 48 hr (or more) in advance of the collection. Click “Submit” on the completed RSST to open an email (with the RSST attached).
	1. To: processing@fredhutch.org and rscourier@scca.org
	2. Edit Subject line by adding “Secure”: SECURE RSST\_RGCODE\_PARTICIPANTID\_VISITDATE
	3. Attachment: RSST\_RGCODE\_PARTICIPANTID\_VISITDATE (the filename of the locally saved RSST)
	4. Send the secure email with the attached RSST.