

## Research Institutional Overhead Collection Process Q & A

### What does the institutional overhead collection schedule look like?

Starting April 1, 2022, the Department of Evaluation and Research Services (DERS) will collect the overhead fees every April, August and December for study visits/procedures that occur during the period of December through March, April through July, and August through November, respectively.

To facilitate the invoicing process and to increase transparency of overhead fees for both DERS and the principal investigators, DERS will use either the Clinical Trial Management System (CTMS) report or the Study Schedule and Payment Form (SSPF) to calculate the overhead fees for each period. Unless the study has been exempted by DERS, all sponsored research studies (both industry and grant-funded studies) will be required to use the CTMS. Any study that is not entered in the CTMS is required to complete the SSPF.

### How does the SSPF work?

DERS will send the principal investigator and the research team the SSPF template prefilled with the study visit schedule and budget as indicated in the research agreement once the Letter of Authorization to Conduct Research (LOA) has been issued. Throughout the study, the principal investigator or their delegate must complete this form to record completed subject enrollment and study visits, including screen-failed subjects, unscheduled visits and conditional procedures in the Study Schedule tab of the SSPF.

STUDY SCHEDULE AND PAYMENT FORM (SSPF)						
STH#B #	[Completed by DERS] ex. FHEB 2018-001					
Study Title	[Completed by DERS] ex. COVID-19 Study					
PI or PI Name	[Completed by DERS] ex. Dr. Bonnie Henry					
Sponsor	[Completed by DERS] ex. Pfizer					
Enrollment Target	[Completed by DERS] ex. 100					
LOA Date	1-Dec-18					
<p><b>Instructions:</b></p> <p>1. DERS will send the SSPF to the Fraser Health Principal Investigator when the study has received Letter of Authorization (LOA).</p> <p>2. The Fraser Health Principal Investigator will update Part 1 throughout the study period.</p> <p>3. DERS will request the updated SSPF every 4 months in April, August, and December, until study closure for overhead collection.</p>						
<p><b>Part 1: Actual Visit Schedules + Conditional Procedures</b></p> <p>To PI or their delegate:</p> <p>Please enter the Subject ID's (in row 13 i.e., column labeled XXX1, XXX2, XXX3)</p> <p>For each subject, add the date when each of the visit/procedure was actually completed.</p> <p>For the Conditional Procedures (ex. Premature discontinure, unscheduled visit), enter the number of times the procedure were conducted for each subject.</p>						
			Subject ID			(insert subject)
Study Visits	Window (days)	Sample Schedule	XXX1	XXX2	XXX3	
Screening	N/A	1-Jan-21	20-Feb-21	12-Dec-20		
Baseline	N/A	3-Jan-21	3-Mar-21	29-Dec-20		
Visit 1	30	2-Feb-21	24-Mar-21	27-Jan-21		
Visit 2	56	2-Mar-21	25-Apr-21	24-Feb-21		
Visit 3	84	30-Mar-21	24-May-21	24-Mar-21		
Visit 4	112	27-Apr-21	21-Jun-21	11-Apr-21		
Visit 20	140	25-May-21	19-Jul-21	9-May-21		
Visit 24	168	22-Jun-21	18-Aug-21			
End of Study	203	27-Jul-21	20-Sep-21			
Premature discontinure	N/A					
Unscheduled visit	N/A					
Conditional Procedures	Example	Subject ID	Column2	Column3	Column4	(insert subject)
Additional Treatment	Example	XXX1	XXXX2	XXXX3		
Clinic pregnancy test						
Brain MRI w/o contrast						
Brain MRI w/ contrast						
MRI spinal, cervical w/o contrast						
MRI spinal, cervical w/ contrast						
MRI spinal, thoracic w/o contrast						
MRI spinal, thoracic w/ contrast						

Figure 1: SSPF Study Schedule Tab

STUDY SCHEDULE AND PAYMENT FORM (SSPF)										
STH#B #	[Completed by DERS] ex. FHEB 2018-001						PI's Signature	CTM Manager's Signature		
Study Title	[Completed by DERS] ex. COVID-19 Study									
PI or PI Name	[Completed by DERS] ex. Dr. Bonnie Henry									
Sponsor	[Completed by DERS] ex. Pfizer									
Enrollment Target	[Completed by DERS] ex. 100									
Overhead Coll Rate	[Completed by DERS] ex. 10%									
LOA Date	1-Dec-18									
<p><b>Instructions:</b></p> <p>1. DERS will send the SSPF to the Fraser Health Principal Investigator when the study has received Letter of Authorization (LOA).</p> <p>2. The Fraser Health Principal Investigator will update Part 1 throughout the study period.</p> <p>3. DERS will request the updated SSPF every 4 months in April, August, and December, until study closure for overhead collection.</p>										
<p><b>Part 2: Actual Payments Per Visit</b></p> <p>This table auto-calculates fees based on the cost per visit and the actual number of subject visits performed during the collection time period on the actual visit schedule table entered in Part 1: Actual Visit Schedule.</p>										
Costs (dependent on date of acquisition)	Germany	USA								
Start Date	1-Jan-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22
Study Visits	Total Cost	# of visits completed	# of visits general	Total Cost	# of visits general	# of visits general	Total Cost	# of visits general	Total Cost	# of visits general
Screening	\$ 9,000.00	21	18,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Baseline	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Visit 1	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Visit 2	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Visit 3	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Visit 4	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Visit 20	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Visit 24	\$ 2,000.00	21	4,000.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Premature discontinure	\$ 3,000.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Unscheduled visit	\$ 3,000.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<p><b>TOTAL REVENUE (Study Visits)</b> \$ 70,000.00</p> <p><b>TOTAL REVENUE (Study Visits) to Fraser Health Authority every 4 months</b> \$ 7,000.00</p>										
Start Date	1-Jan-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22	1-Jul-22
Conditional Procedures	Total Cost / Procedure	# of procedures completed	Total Cost	# of procedures / general	Total Cost	# of procedures / general	Total Cost	# of procedures / general	Total Cost	# of procedures / general
Clinic pregnancy test	\$ 1,500.00	0	\$ 0.00	0	\$ 0.00	0	\$ 0.00	0	\$ 0.00	0
Brain MRI w/o contrast	\$ 3,000.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Brain MRI w/ contrast	\$ 3,000.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
MRI spinal, cervical w/o contrast	\$ 2,500.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
MRI spinal, cervical w/ contrast	\$ 2,500.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
MRI spinal, thoracic w/o contrast	\$ 2,500.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
MRI spinal, thoracic w/ contrast	\$ 2,500.00	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<p><b>TOTAL REVENUE (Conditional Procedures) to Fraser Health Authority every 4 months</b> \$ 0.00</p> <p><b>TOTAL REVENUE (All)</b> \$ 70,000.00</p> <p><b>TOTAL REVENUE (All) to Fraser Health Authority every 4 months</b> \$ 7,000.00</p>										

Figure 2: SSPF Overhead Collection Tab

Every April, August and December, DERS will collect the updated SSPF forms from the principal investigator to calculate the institutional overhead fee using the calculation in the Overhead Collection tab of the SSPF.

A new Overhead Collection tab will be created for each amendment to the budget.

Please contact [research.contracts@fraserhealth.ca](mailto:research.contracts@fraserhealth.ca) if you have any questions regarding the completion of the SSPF.

### How does DERS use the CTMS to calculate the overhead fees?

For studies using the CTMS for study management, the principal investigator and the research team will update subject enrollment and study visits in the CTMS throughout the study.

Every April, August and December, the CTMS coordinator will generate a CTMS report ([Study Financial Detail – Tabbed Export report](#)) from the system to calculate the institutional overhead fee.

**How to add your study to the CTMS?**

Fraser Health [requires](#) all funded studies (including both industry-sponsored and grant-funded trials) to be added to the CTMS. Please complete the CTMS Intake Event Form in ROMEO to add your study to the CTMS. The CTMS Coordinator will create the study template once the LOA has been issued.

Please contact [CTMS@fraserhealth.ca](mailto:CTMS@fraserhealth.ca) if you have any questions or issues with the CTMS or visit [CTMS SharePoint](#) for resources.

Sponsor	Protocol	Visit Name	Random No	Visit Date	Non-Overhead Revenue	Payments Received	Payment Date	Balance Due
Pfizer	TE123	Screening	101	08/Jan/2020	\$2,935.00	\$3,898.00	15/Jun/2020	\$-97.50
Pfizer	TE123	Week 1 Day 1	101	05/Feb/2020	\$760.00	\$988.00	15/Jun/2020	
Pfizer	TE123	Week 1 Day 2	101	06/Feb/2020	\$280.00	\$364.00	15/Jun/2020	
Pfizer	TE123	Week 1 Day 3	101	07/Feb/2020	\$280.00	\$364.00	15/Jun/2020	
Pfizer	TE123	Week 4	101	04/Mar/2020	\$600.00	\$780.00	15/Jun/2020	
Pfizer	TE123	Week 8	101	01/Apr/2020	\$700.00	\$910.00	15/Jun/2020	
Pfizer	TE123	Week 16	101	27/May/2020	\$2,840.00	\$3,677.00	15/Jun/2020	\$338.00
Pfizer	TE123	Week 24	101	21/Jun/2020	\$260.00	\$0.00		\$338.00
Pfizer	TE123	Week 26	101	05/Aug/2020	\$2,840.00	\$0.00		\$3,677.00
Pfizer	TE123	Week 32	101	16/Sep/2020	\$260.00	\$0.00		\$3,677.00
Pfizer	TE123	Week 40	101	11/Nov/2020	\$680.00	\$0.00		\$897.00
Pfizer	TE123	Week 52	101	03/Feb/2021	\$2,690.00	\$0.00		\$3,482.00
Pfizer	TE123	Week 56	101	03/Mar/2021	\$380.00	\$0.00		\$455.00
Pfizer	TE123	Screening	102	13/Jan/2020	\$2,985.00	\$3,888.50	15/Jun/2020	
Pfizer	TE123	Week 1 Day 1	102	27/Jan/2020	\$760.00	\$988.00	15/Jun/2020	
Pfizer	TE123	Week 1 Day 2	102	28/Jan/2020	\$280.00	\$364.00	15/Jun/2020	
Pfizer	TE123	Week 1 Day 3	102	29/Jan/2020	\$280.00	\$364.00	15/Jun/2020	
Pfizer	TE123	Week 4	102	10/Feb/2020	\$600.00	\$780.00	15/Jun/2020	
Pfizer	TE123	Week 8	102	09/Mar/2020	\$700.00	\$910.00	15/Jun/2020	
Pfizer	TE123	Week 16	102	04/May/2020	\$2,840.00	\$3,677.00	15/Jun/2020	
Pfizer	TE123	Week 24	102	29/Jun/2020	\$260.00	\$338.00	15/Jun/2020	
Pfizer	TE123	Week 26	102	13/Jul/2020	\$2,840.00	\$0.00		\$3,677.00
Pfizer	TE123	Week 32	102	07/Sep/2020	\$260.00	\$0.00		\$338.00
Pfizer	TE123	Week 40	102	19/Oct/2020	\$680.00	\$0.00		\$897.00
Pfizer	TE123	Week 52	102	11/Jan/2021	\$2,690.00	\$0.00		\$3,482.00
Pfizer	TE123	Week 56	102	22/Feb/2021	\$380.00	\$0.00		\$455.00
Pfizer	TE123	Reconsenting 1	102	09/Mar/2020	\$100.00	\$100.00	15/Jun/2020	
Pfizer	TE123	SAE 1	102	07/Sep/2020	\$250.00	\$0.00		\$250.00
Pfizer	TE123	Screening	103	04/Feb/2020	\$1,010.00	\$1,313.00	15/Jun/2020	\$1,280.50
Pfizer	TE123	Screening	103	09/May/2020	\$985.00	\$0.00		\$988.00
Pfizer	TE123	Week 1 Day 1	103	21/Sep/2020	\$760.00	\$0.00		\$988.00
Pfizer	TE123	Week 1 Day 2	103	22/Sep/2020	\$280.00	\$0.00		\$364.00
Pfizer	TE123	Week 1 Day 3	103	23/Sep/2020	\$280.00	\$0.00		\$364.00
Pfizer	TE123	Week 4	103	19/Oct/2020	\$600.00	\$0.00		\$780.00
Pfizer	TE123	Week 8	103	16/Nov/2020	\$700.00	\$0.00		\$910.00
Pfizer	TE123	Week 16	103	11/Jan/2021	\$2,840.00	\$0.00		\$3,677.00
<b>TOTAL:</b>					<b>\$38,825.00</b>	<b>\$23,695.50</b>		<b>\$26,502.00</b>
<b>O/H fee payable to Fraser Health Authority at the REB Annual Renewal</b>					<b>\$3,882.50</b>	<b>\$2,369.55</b>		<b>\$2,655.20</b>
<b>CTMS Manager's Signature</b>					<b>Fraser Health PI's Signature</b>			
<input type="text"/>					<input type="text"/>			

Figure 3: CTMS Report

**What does the invoicing process look like?**

Once DERS receives the completed SSPF or CTMS Report, DERS will calculate the institutional overhead fees and send a PDF copy of the SSPF or CTMS report for both the principal investigator and the Manager, Clinical Trials and Business Development to review and sign.

DERS recognizes that there may be circumstance where the funds from the sponsor/funder are not available until the sponsor has paid. Please indicate in the PDF copy of the SSPF or CTMS report the amount you will be paying at this time.

Once DERS receives the signed report, the Fraser Health Treasury will issue the invoice to the principal investigator and/or research site. The principal investigator and/or research site must submit the payment to Fraser Health's Treasury.

Please contact Raman Sran, DERS Program Assistant ([Raman.sran@fraserhealth.ca](mailto:Raman.sran@fraserhealth.ca)) with any questions regarding the invoices.

**What if the budget is in a foreign currency?**

If the budget is in another currency besides Canadian dollars and the study is in the CTMS, DERS will calculate the institutional overhead fees for study items that have been paid by the sponsor and will use the same exchange rate applied on that sponsor payment.

If the study is not in the CTMS, the Fraser Health treasury department will use the exchange rate on the day the invoice is being issued.

**Questions?**

Please contact Patrick Altejos, Manager, Clinical Trials and Business Development ([Patrick.Altejos@fraserhealth.ca](mailto:Patrick.Altejos@fraserhealth.ca)) with any questions or concerns.