#### Sykehusinnkjøp HF

Organisasjonsnummer 916 879 067 Telefon 78 95 07 00 post@sykehusinnkjop.no Sykehusinnkjøp HF, Postboks 40, 9811 Vadsø

# Agreement

2020xxxxxxx [Name of agreement]



# Signature page

#### Parties to the contract:

	Customer	Supplier
Company name:	Oslo University Hospital HF	
Org. no.:	993 467 049	
Company address:	Kirkeveien 166 (Building 1) 0450 Oslo	

Contract manager: Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF)

# **Contract period:**

The contract runs from the time of signing until all the services is successfully performed and accepted by the customer.

This framework agreement is electronically signed by:

for Customer	for Supplier
[Tittel] [Navn]	[Tittel] [Navn]
[Tittel] [Navn]	[Tittel] [Navn]



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# 1 General provisions

#### 1.1 Scope and purpose of contract

The purpose of the contract is to cover Oslo University Hospital's needs for in vitro and in vivo testing for contaminations for the establishment of a Master Cell Bank of a lentivirus-transduced human cell line. The cell line will be used as feeder cells in the production of a cell-therapeutic product for cancer therapy and needs to follow the EMA and FDAs guidelines for raw materials for production of cell-therapeutic products.

#### 1.2 Parties to the contract

The parties to the contract are as shown on the front page of the contract and are referred to in the contract as Customer and Supplier respectively.

If there is a restructuring of the health trusts, a change in the ownership of the health trusts, a change in the regional structure, etc. during the term of contract, the health trusts' legal successors will be able to enter into the agreement on current terms.

Having concluded the contract, the Supplier may not assign its rights or obligations without the Customer's consent in writing, such consent not to be refused unreasonably.

#### 1.3 Contract documents:

The contract documents are as follows:

All entries must be crossed off (yes/no)	Yes	No
Framework agreement (this document)	Х	
Appendix 1 Price document	Х	
Appendix 2 Requirements specification (with the supplier's answer)	Х	
Appendix 3 Options (amendments)	Х	
Appendix 4 Ethical business requirements		Х
Appendix 5 Guidelines for correct basic data in [Health South-East] RHF		Х
Appendix 6 Amendments to contract since concluded	Х	

#### 1.4 Interpretation of documents and order of precedence

If there is any conflict, the documents apply in the order of precedence below:

- 1. Appendix 6 Amendments to contract since concluded
- 2. Contract (this document)
- 3. Appendix 1 Price document
- 4. Appendix 2 Requirements specification (with the supplier's answer)
- 5. Appendix 3 Options (amendments)
- 6. Appendix 4 Ethical business requirements
- 7. Appendix 5 Guidelines for correct basic data in [Health South-East] RHF

Any matters the contract does not cover are covered by the Law on purchasing of 13 May 1988 no. 27 (purchasing law).



### 1.5 Parties' representatives

Turnes repre	Customer	Supplier
Full company name	Oslo University Hospital HF	
Postal address:	P.O. Box 4950 Nydalen 0424 Oslo	
Tel. (switchboard):	915 02770	
Website:	www.oslo-universitetssykehus.no	
Contract manager:	The Norwegian Hospital Procurement Trust Name Division/department	
Visitors' address:	Forskningsveien 2B, 3rd floor 0373 Oslo	
Tel.:		
Mobile:		
E-mail:	xxx@sykehusinnkjop.no	
Specialist contact:	Name Department	
Visitors' address:		
Tel.:		
Mobile:		
E-mail:		
Contact person of ordering	Purchaser stated on the order	

#### 1.6 Term of contract

The agreement covers the period shown on the signature page of the contract.

The contract is considered fulfilled when all tasks are performed and accepted by the Customer.

#### 1.7 Termination by notice

The contract cannot in general be terminated by neither of the parties. However, if unforeseen difficulties with the cell line occur, such as failing to establish the cell line or early test results detects contamination, the Customer have the right to cancel remaining analyses that have not been performed.



# 2 Ordering and reporting

#### 2.1 Ordering process and time schedule

Activity	Performed by	Time/deadline
	Customer	Within a reasonable time after
Establish the cell line		signing the contract
Notify the Contractor that the cell line is	Customer	
ready to be shipped and request date for		When the cell line is ready
shipping.		
	Supplier	Within a week after receiving the
Report back when the testing of the cell line		notification that the cell line is
can begin and time for shipping.		ready to be shipped
De ferror de la descripción de la Company	Customer	When Supplier has confirmed time
Perform an electronic order in iProc	Contant	of shipping
Send the cell line as agreed	Customer	On agreed time of shipping
Confirm that the cell line has been	Supplier	Immediately after the cell line has
successfully received. Deviations must be		been received
reported immediately	Customer	X days/weeks after deviations has
If applicable: Do necessary adjustments	Customer	been reported
Perform the analysis as described, following	Supplier	Follow the timeline stated in the
the work plan	Заррнен	workplan
Checkpoint: Report back the results from the	Supplier	·
first performed tests, in order to continue		When the first results are ready
	Customer	X days/weeks after receiving the
Confirm whether to continue testing or not		first test results
Prepare and send Report of Analysis to the	Supplier	X weeks
Customer		A WEEKS
Approve Report of Analysis	Customer	X weeks
Send invoice in EHF-format	Supplier	
Process and pay invoice	Customer	30 days after received invoice

#### 2.2 Turnaround Time

The maximum elapsed time from receipt of samples to final report is [to be filled in from/based on the tender]

#### 2.3 Delay of results

If the Supplier has reason to believe that agreed turnaround time cannot be met, it must inform the Customer in writing immediately, stating why the delay has occurred and how long it is expected to last and what it proposes to do to limit it. The Supplier must cover its own costs incurred in limiting the delay unless these are attributable to the Customer. The Supplier is responsible for losses the Customer suffers due to the delay unless it is attributable to the Customer.

#### 2.4 Reporting of results

Test results should be documented as stated in Annex 2.



#### 3 Prices

#### 3.1 Definition of prices

Unless Annex 1 states otherwise, all prices must be stated in Euros excluding VAT but including all costs regarding the performance of requested analysis, reporting the answers, invoicing costs, customs, taxes and other duties.

#### 3.2 Price reviews in case of unforeseeable difficulties

If additional work will be required due to unforeseeable difficulties related to the customers samples, the additional work shall not start until the economic consequences are agreed upon by the parties.

## 4 Quality and standards

#### 4.1 Quality requirements and standards

All analysis needs to follow the EMA and FDAs guidelines for raw materials for production of cell-therapeutic products.

The analysis stated in the Annex 1 must be performed according to the principles of Good Manufacturing Practice (GMP) where this is required.

# 5 Supplier's obligations

#### 5.1 Supplier's responsibility

The Supplier is responsible for meeting the requirements stated in Annex 2.

When the Supplier confirms that the cell line has been successfully received and the quality of the material is approved, the Supplier is responsible for performing the requested analysis to the agreed price.

The Supplier is fully liable for performing the contract, even if it engages others to perform it on its behalf.

The Supplier will keep the Customer continuously up to date on changes to the organisation, procedures and the like which affect the execution of the contract.

#### 5.2 Performance liability

The Supplier agrees to hold the Customer harmless against any and all claims, including claims for costs in the case, which third parties bring against the Customer and which are due to faults in performance or the Supplier's injurious act.

#### 5.3 Professional assistance

The Supplier agrees to provide relevant professional assistance, such as answering professional analysis-related questions and providing guidance in the interpretation of test results. Such assistance will preferably be given by e-mail or telephone.

This applies throughout the term of the contract at no extra charge to the Customer.



#### 5.4 Invoicing

Invoices and underlying details must be specified and recorded in such a way that they can be verified without using significant resources on the Customer's part. The invoices must include the the P.O number from the Customers ordering system.

No invoicing charges or supplements may be charged of any kind.

If it is agreed that the Supplier may use subcontractor(s), the Supplier will still be responsible for the invoicing.

If the Customer invoiced incorrectly or invoices are faulty, it will be entitled to new correct invoices with new due dates.

Significant and/or repeated invoicing errors will be regarded as a breach of contract.

#### 5.5 Electronic invoicing

The Supplier must be able to issue invoices, credit notes and reminders if any in accordance with current e-commerce formats at any time, and must bear any costs issuing electronic invoices involves.

#### 5.6 Marketing

The Supplier must obtain the Customer's advance consent in writing if it wishes to disclose details of the contract or use the Customer's name and logo for advertising purposes or otherwise.

#### 5.7 Audits

The Customer or its appointed agents may audit the Supplier's systems, procedures and activities relating to the deliveries. These audit rights will start when the contract is concluded and be limited to its term. The Supplier will assist reasonably with audits free of charge.

# 6 Customer's obligations

#### 6.1 Payment

Payment will be made 30 calendar days after report issuance is made in accordance with the contract and a correct invoice has been received unless other payment terms are agreed.

Payment does not imply accepting fulfilment of the contract.

If payment is late, the Supplier may claim late interest under the late interest law of 17 December 1976 no. 100.

We will not accept any processing, invoicing or other such charges from the Supplier.

#### 6.2 Customer's assistance

The Customer will assist the Supplier as required to enable it to meet its obligations to deliver.

# 7 Obligations on both Customer and Supplier

#### 7.1 Confidentiality obligations

The parties are subject to confidentiality obligations under § 13 et seq. of the Norwegian Public Administration Act. Each party must ensure amongst other things ensure that others do not become aware of information that emerges about the other's business or personal matters. This shall not



prevent such information being given to others if this is necessary to perform the contract. If the contract involves elements of providing services at the Customers premises, the Supplier must sign a confidentiality undertaking before it is allowed access to the Customer's premises.

#### 7.2 Loyalty

For the healthcare company to serve its purpose, namely, to contribute to more cost-effective operations, the Customer must monitor and use the contract. On the other hand, the Supplier is not expected to deliver services to the Customer which it knows will be contrary to procurement rules.

#### 7.3 Obligation to inform if there are suspicions of corruption

The hospital's contract partners are obliged to report if they suspect or know of any acts which come under the provisions on corruption. Reports may be made anonymously.

E-mail reports to: <a href="mailto:varsling@oslo-universitetssykehus.no">varsling@oslo-universitetssykehus.no</a>

Tel.: Switchboard 02770 (inland) or +47 915 02770 (abroad) and ask for Reporting services in the

legal department

Post: Reporting service, legal director, Oslo University Hospital HF, Ullevål Hospital, P.O. Box 4956

Nydalen, 0424 Oslo

For details of the Hospital's reporting service, go to: www.oslo-universitetssykehus.no

# 8 Breaches by the Supplier

#### 8.1 What constitutes a breach?

The Supplier will be deemed to be in breach of the contract if it fails to meet requirements and deadlines agreed, or if it fails to meet its other obligations under the contract.

There is no breach if the situation is due to matters on the Customer's part or to force majeure.

The Customer must complain within a reasonable time from when it discovered or ought to have discovered breaches.

#### 8.2 Supplier's duty to inform

In cases of breach, the Supplier must inform the Customer in writing as soon as possible, stating what caused the breach and when it can be expected to end if possible, likewise if there are expected to be any further breaches once the first notice is given.

#### 8.3 Remedying matters

The Supplier must start and implement work remedying the breach with all due speed.

The aim of remedying matters is that deliveries must meet agreed requirements and specifications, such as by making good, redelivering or additional deliveries. Matters must be remedied at no expense to the Customer.

The Customer may refuse to have matters remedied if it would be disproportionately inconvenient to it.

Insofar as matters cannot be remedied, the Customer may demand that prices be reduced pro rata or cancel the order in accordance with the terms on reducing prices and termination due to breach.



Should the Supplier fail to remedy the breach within the time foreseen or agreed, or should the conditions for termination due to breach apply, the Supplier will cover the Customer's costs with the aid of third parties. The Customer will notify the Supplier in writing before engaging any third parties.

#### 8.4 Penalties

#### 8.4.1 Withholding payment

In the event of a breach, the Customer may withhold payment, but not obviously more than is necessary to secure its claims resulting from the breach.

#### 8.4.2 Reducing prices

Should the Supplier fail to rectify defects despite repeated attempts, the Customer may demand that the order price value be reduced pro rata. Reducing prices is compensation for the reduced value of what was supplied, and is without prejudice to any compensation or daily penalties.

#### 8.4.3 Liquidated damages

The Customer may claim liquidated damages for any direct losses which can be reasonably attributed to any delay, defect or other breach on the Supplier's part.

Daily penalties will be deducted from any liquidation damages for the same delay.

#### 8.4.4 Limitation of liquidated damages

No liquidated damages can be claimed for indirect losses.

The total liquidated damages during the term of the contract are limited to the equivalent of the upper value of the contract including options (excluding VAT).

Should the Supplier or anyone for whom it is responsible be guilty of gross negligence or intent, the damage limitations stated in this section will not apply.

#### 8.4.5 Daily penalties

Delays will be subject to daily penalties unless Annexe 1 states otherwise. Daily penalties will accrue without proving losses and irrespective of any other penalties imposed on the Supplier.

The daily penalty will be 1% of the contract price excluding VAT, but subject to a minimum of NOK 500.00 per calendar day until delivery is made according to the contract. The total daily penalties may not exceed 15% of the contract price.

The Customer cannot terminate the contract while daily penalties are running, except if the Customer or anyone for whom it is liable is guilty of gross negligence or intent.

If only part of an order is delayed, the Supplier may demand that the daily penalties be reduced pro rata insofar as the Customer can use that part of the service which was delivered.

#### 8.4.6 Termination due to material breach

If there is a material breach, having warned the Supplier in writing and given it a reasonable period in which to remedy matters, the Customer may terminate the contract with immediate effect.

When terminating the contract, the Customer may claim liquidated damages for other losses which cannot be claimed under the rules on penalties for breach for orders/call offs made.



8.4.7 Termination of contract in connection with insolvency etc.

Should insolvency, composition or bankruptcy proceedings be opened in respect of the Supplier's business, or should it seek protection from its creditors otherwise, the Customer may terminate the contract with immediate effect.

# 9 Breaches on Customer's part

#### 9.1 How breach is defined

The Customer is in breach if it fails to meet its obligations under the contract.

There is no breach, however, if the situation is due to matters on the Supplier's part or which are deemed to be force majeure.

The Supplier must complain in writing with all due speed once it has discovered or should have discovered the breach.

#### 9.2 Restrictions on Supplier's right to withhold

The Supplier may not withhold services in consequence of a breach on the Customer's part unless the breach is of the essence and the Customer has admitted it in writing or it has been established by way of one of the dispute resolution mechanisms in section 12.

#### 9.3 Termination due to breach

If the Customer is in breach with payments, the Supplier may terminate the contract unless the Customer pays what is due within 30 calendar days of receiving the Supplier's notice in writing.

If the Customer is in material breach otherwise, the Supplier may notify the Customer in writing that the contract will be terminated unless the Customer remedies matters within 60 days of receiving that notice.

It may not terminate if the Customer remedies matters within the time allowed.

#### 9.4 Compensation

The Supplier may demand to be compensated for any direct losses which may reasonably be attributed to the breach.

The provisions of the contract on limitations of damages in section 9.4.5 will apply mutatis mutandis.

# 10 Force majeure

Should an extraordinary situation arise which is beyond the control of the parties, which makes it impossible to meet their obligations under this contract and which must be deemed to be force majeure as defined in Norwegian law, the other party must be informed of this as soon as possible. The obligations of the affected party are suspended for as long as the extraordinary situation persists; the other party's consideration will be suspended for the same period.

In a force majeure situation, the other party can only terminate the contract with the affected party's consent, or if the situation is expected to persist for more than 90 calendar days from when it arose and then only at 15 calendar days' notice.

In connection with force majeure situations, the parties will be bound to inform one another of all matters which may be assumed to be material to the other party. Such information must be given as soon as possible.



# 11 Choice of law and dispute resolution

#### 11.1 Choice of law

The parties' rights and obligations under this contract will be governed entirely by Norwegian law.

#### 11.2 Negotiation

Should a dispute arise between the parties as to the interpretation of the contract or its effects in law, they will seek to resolve it by way of negotiation in the first instance.

#### 11.3 Mediation

If a dispute cannot be resolved by negotiation, the parties may seek to resolve it by mediation.

The parties may opt to apply the Norwegian Bar Council's rules for mediation by advocate modified as they require. It is assumed that the parties agree on a mediator with the competence the parties believe is best suited in relation to the dispute.

The mediator will decide on the more detailed rules on how to proceed with the mediation in consultation with the parties.

#### 11.4 Referring matters to courts

If matters cannot be settled by negotiation or mediation, they will be decided by the ordinary courts.

In the case of a statement of claim or arbitration in respect of the contract, the Customer's general jurisdiction will apply.





# Appendix 3 Options to Agreement no xxxxxxxxxx

# Increase in range of analysis

The Client has the right to add additional analysis to Annex 1 if required by new EMA and FDAs guidelines for raw materials for production of cell-therapeutic products.

- The additional analysis shall be priced accordingly.
- The additional analysis requires a new time schedule.