**PHARMACY AGREEMENT**

This Pharmacy Agreement (“**Agreement**”) is entered into by and between

1. [SPONSOR AS], located at [address]  (“**Sponsor**”), and
2. XXXXXX Hospital Pharmacy, located at [address] (“**Pharmacy**”)

Each a **Party** and jointly the **Parties**.

**BACKGROUND**

1. WHEREAS, This Agreement specifies distinct pharmacy services (**Services**) to be delivered by Pharmacy in relation to the conduct of STUDY TITLE (**Study**) at Name and full address of institution (**Institution**), in strict adherence to Protocol No. XXXXXXXXX (**Protocol**), which is sponsored by Name and full address of sponsor if CRO is one of the Parties above (**Sponsor**).
2. WHEREAS, The Investigational Product for this study, XXXXXXXXXXX (**Study Drug**), will be handled by the Pharmacy according to specifications in this Agreement.
3. WHEREAS, Inven2 AS, located at Forskningsparken, Gaustadalléen 21, 0349 Oslo, Norway, is authorized to negotiate the Agreement on behalf of Pharmacy.
4. WHEREAS, The negotiation of payments/compensation, to be specified in Exhibit A of this Agreement, is handled directly between the Sponsor and the Pharmacy
5. WHEREAS, Name and full address of CRO, (“**CRO**”) have been authorized by Sponsor to negotiate this Agreement, including payments/compensation to be specified in Exhibit A of this Agreement, on behalf of Sponsor. The negotiation of payments/compensation, to be specified in Exhibit A of this Agreement, is handled directly between the CRO and the Pharmacy
6. COMPLIANCE WITH LAW

## The Pharmacy shall perform the Services in accordance with all applicable laws, regulations and guidelines, the directions of Sponsor, the terms of this Agreement and the Study Protocol.

1. STUDY DRUG and EQUIPMENT, Study Drug IMPORT AND EXPORT

## Pharmacy shall provide Services relating to the Study and Study Drug in accordance with the terms of this Agreement and as specified in Exhibit A, by using Pharmacy personnel only, and according to internal procedures at the Pharmacy:

## The Sponsor shall provide Pharmacy with sufficient quantity of Study Drug. In this agreement Study Drug should be defined as all medicinal products used in the Study, whether investigational or non-investigational and regardless of source, including placebo. All such Study Drug is and shall remain the sole property of Sponsor. Pharmacy shall keep a record of all dispensation of the Study Drug. In particular, Pharmacy shall keep record of all accepted, stored, distributed, liquidated, and returned Study Drug. These records shall include the date, amount, batch number, expiration date and code numbers.

## If the Performance of the Services requires any particular equipment that Pharmacy does not possess, Sponsor must provide such equipment and shall be responsible for its qualification, validation and maintenance for the duration of the Services. Pharmacy shall not be liable in any way for such equipment, hereunder liable in case of loss or damage, unless Pharmacy has acted with gross negligence or willful misconduct. Sponsor will assist Pharmacy in maintaining the equipment in good working order at Sponsors expense. All such equipment shall be listed in the Exhibit A and shall be returned to Sponsor at the end of the Study. Pharmacy can only use such equipment for purposes of the Services.

## Import by Sponsor: If Sponsor is responsible for the import of Study Drug (ref Exhibit A to this Agreement); Sponsor must ensure that all relevant documents for the import are in order and that Sponsor is recognized as the importer in all import documents. Sponsor must present necessary documentation to the Pharmacy of Sponsor’s or Sponsor’s representatives’ authorisation for such import.

## Import by Pharmacy: If Pharmacy is responsible for the import of Study Drug (ref Exhibit A to this Agreement), all of the following apply:

## Sponsor must present the necessary license documents and certificates, either from a licensed wholesaler (with Wholesale Distribution Authorisation (WDA) and GDP certificate) or from an approved manufacturer (with Manufacturing and importations Authorisation (MIA) and GMP certificate) within the EEA. Study Drug (IMP) must be included in these license documents.

## Sponsor will provide the Pharmacy with a batch release document for each batch of Study Drug (IMP), signed by Qualified Person (QP). The batch release document can be sent with the Study Drug (IMP), or by e-mail to the Pharmacy’s contact person.

## Sponsor is responsible for packing and shipping of Study Drug (IMP) in a proper manner, so that quality and storage conditions are maintained during transport until arrival and receipt at pharmacy, safety is ensured and that all applicable regulations are met including “The Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use” (GDP) chapter 7 and 9. Sponsor confirms they have entered into a Quality Agreement with the responsible entity for such transport of Study Drug, and will provide Pharmacy with a copy of the Quality Agreement and other documents related to transport, validation and quality, if requested.

## If Sponsor ships Study Drug (IMP) without temperature logs attached, the Sponsor must provide evidence that temperature during transportation is acceptable and does not affect the quality of the Study Drug (IMP).

## Pharmacy shall not have any financial and/or other responsibility for any damage that may happen to goods and/or third parties or receiver in conjunction with the shipping of the Study Drug.

## Sponsor agrees that the Pharmacy is not liable for any damage to the drug in transit.

## Sponsor will cover all costs, including but not limited to transport and shipping, customs fees and VAT.

## Sponsor will instruct the responsible shipper (Provider) that all shipments should be clearly marked “For clinical trial use” and that Provider should include in every shipment documentation showing that the shipment contains only medications for use in clinical trial, including a copy of approval for this Protocol by the Norwegian Medicines Agency (NoMA).

## Sponsor will instruct the Provider to address shipments to the Pharmacy at address agreed for this protocol, never to the Hospital or the Principal Investigator

## Sponsor will instruct the Provider to name the Pharmacy as Study Drug Importer of record on shipment documents.

## Export by Pharmacy: If Pharmacy is responsible for the export of Study Drug for return and/or destruction (ref Exhibit A to this Agreement), all of the following apply:

## Sponsor must present the necessary license documents and certificates for the receiver, either from a licensed wholesaler (with Wholesale Distribution Authorisation (WDA) and GDP certificate) or from an approved manufacturer (with Manufacturing and Importations Authorisation (MIA) and GMP certificate) within the EEA. Study Drug (IMP) must be included in these license documents.

## Sponsor will provide the Pharmacy with the relevant documents for return of study drugs, including proforma invoice, air waybill (AWB) (if applicable).

## Sponsor is responsible for packing and shipping of Study Drug (IMP) in a proper manner, so that quality and storage conditions are maintained during transport until arrival and receipt at receiver, safety is ensured and that all applicable regulations are met including GDP chapter 7 and 9. Sponsor confirms they have entered into a Quality Agreement with the responsible entity for such transport of Study Drug, and will provide Pharmacy with a copy of the Quality Agreement and other documents related to transport, validation and quality, if requested.

## If temperature surveillance is needed during transport, Sponsor is responsible for providing necessary equipment such as temperature loggers and packing material.

## Pharmacy shall not have any financial and/or other responsibility for any damage that may happen to goods and/or third parties or receiver in conjunction with the shipping of the Study Drug.

## Sponsor agrees that the Pharmacy is not liable for any damage to the drug in transit.

## Sponsor will cover all costs, including but not limited to transport and shipping, customs fees and VAT.

## Sponsor acknowledges that Pharmacy does not have an export license and that an application has to be submitted to and approved by NoMA prior to any export can take place. Sponsor will provide necessary information for said application.

## Sponsor may change information and documentation regarding distribution of Study Drug including, but not limited to, shipper’s address, authorization, shipping route etc., provided that such change is in accordance with applicable laws and regulations, and that Pharmacy has accepted the documentation.

## Any other drug, pharmaceutical product or similar, which is needed in a Study but not provided by Sponsor, will be provided by Pharmacy, as specified in the Exhibit A. Any such provision will be paid by Sponsor.

## Any transport of Study Drug and/or any other drug between hospital pharmacies or from Pharmacy to patient must be agreed between Sponsor and Pharmacy as specified in Exhibit A or agreed in writing, and Sponsor will cover all costs related to such transport.

## If the performance of the Services requires special training with regard to Sponsor’s equipment, Study Drug or special procedures, Sponsor/CRO shall provide the necessary training.

1. RETURN OF STUDY MATERIALS

## If the parties agree that the return of such Study Drug is not practicable or is prohibited under local laws or regulations, any remaining or expired Study Drug will be destroyed in full compliance with applicable laws and regulations by either (a) the Pharmacy, provided that Pharmacy has the necessary facilities, expertise and regulatory approvals required to destroy Study Drug; or (b) by a third party contracted by the Pharmacy (approved by Sponsor in its reasonable discretion), provided that the Pharmacy is identified as the generator of the Study Drug and further provided that the Pharmacy confirms that the third party has the necessary facilities, expertise and regulatory approvals required to destroy Study Materials. Upon any such destruction by Pharmacy or by a third party, Pharmacy will promptly provide Sponsor with a certificate of destruction or similar document verifying the final disposition of the Study Drug. Sponsor shall pay Pharmacy for any destruction and/or return of Study Drug in this section.

1. CONTACT PERSONS

## Investigator as an employee of Institution (Investigator and Institution as listed in the table below), will be responsible for the conduct of the Study.

## Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or transmitted by PDF to the address given in this Agreement:

|  |  |
| --- | --- |
| **If to Pharmacy:** | **If to Institution:** |
| **If to Sponsor:** | **If to Investigator:** |
| **If to Inven2:**  Inven2 AS  Gaustadalléen 21  0349 Oslo, Norway  Att: Siri Kolle | **If to Study nurse or any other relevant personnel:** |

1. MONITORING AND ACCESS

## Pharmacy shall, during the Study, permit Sponsor and its designee(s) and representatives of competent authorities to access Pharmacy’s premises to inspect and monitor provision of the Services, as well as to audit records relating to the Services to verify Pharmacy’s compliance with the obligations herein and with applicable laws and regulations. Such access should be arranged at mutually convenient times. The monitor is at his/her first visit at the Pharmacy required to sign a confidentiality disclosure agreement, limiting disclosure of information regarding the Pharmacy, its activities and the staff of the Pharmacy, which the monitor will/may get access to during visits at the Pharmacy.

1. COMPENSATION

## In exchange for the performances of services under this Agreement, Sponsor shall pay Pharmacy as per Exhibit A to this Agreement. Sponsor shall pay Pharmacy after receipt of an invoice detailing Pharmacy’s Services under this Agreement and appropriate receipts of any pass-through expenses. Sponsor will pay Pharmacy within 30 days after the date the invoice is sent from Pharmacy. If invoices are not paid on due date, Pharmacy will add interest according to the Act relating to interest on overdue payments, of 1976 (*Lov om renter ved forsinket betaling m.m*.).

## In the event of termination of this Agreement by Sponsor without cause, Sponsor will pay Pharmacy for Services performed and expenses incurred through the date of termination in accordance with the budgeted amounts set forth in Exhibit A to the Agreement.

## Pharmacy understands that the terms and conditions of this Agreement, including the amount of any payment made thereunder, may be disclosed and made public by Sponsor as required by law or regulation or where Sponsor deems appropriate.

## The Parties acknowledge that the amounts to be paid by Sponsor under this Agreement are reasonable compensation, representing the fair market value, for the work performed by Pharmacy, and that neither of Pharmacy or Pharmacy Staff have received any other compensation or inducement in connection with this Agreement or their participation in the Study.

## Pharmacy agrees that in the event of a payment dispute, Pharmacy shall not withhold Services and/or Study Drug pending resolution of the dispute because such withholding may cause irreparable harm to the patients and/or the Study.

## If, at the date of termination of this Agreement or the Study, the total amount Sponsor has paid is less than the amount to which Pharmacy is entitled hereunder, Sponsor shall pay the amount due Pharmacy within a maximum of 30 days.

## Pharmacy acknowledges and agrees that the payments made by Sponsor under this Agreement represent Sponsor’s total obligations. All payments shall be made in accordance with general accepted accounting principles.

## Any start-up fee will be invoiced upon signing of this Agreement. This fee is a one-time compensation for work performed by Pharmacy in the planning and preparation phase of the Study. The start-up fee will not be refunded should the planned time for enrolment of first Subject not be met, or should no Subjects be enrolled in the study at the Institution.

1. CONFIDENTIALITY

## During the Term (as defined below) of this Agreement and for ten (10) years thereafter, Pharmacy and its employees, agents, subcontractors and affiliates (collectively the “Receiving Party”) shall not disclose Confidential Information without Sponsor’s prior written consent. “Confidential Information” shall include the Study Protocol, information related to Study Drug, and all materials and information concerning Sponsor or the Study disclosed to the Receiving Party by Sponsor or developed as a result of conducting the Study. This applies to all confidential information, except any portion thereof which:

## is known to the Receiving Party before receipt thereof under this Agreement, as evidenced by its written records;

## is disclosed to the Receiving Party after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner; or

## is or becomes part of the public domain through no fault of the Receiving Party.

## The Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Sponsor’s prior written approval.

## During the Term of this Agreement and thereafter, the Receiving Party shall not use Confidential Information for any purpose other than that indicated in this Agreement without Sponsor’s prior written approval.

## Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Sponsor prompt written notice (and in any case at least five (5) business days’ notice), to the extent permitted by law or regulation, to allow Sponsor to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Sponsor waives compliance with the terms of this Section 7, Receiving Party shall furnish only that portion of the Confidential Information which is legally required.

## None of the Parties will disclose to the other Party any information which is confidential or proprietary to a third party unless Pharmacy has first obtained the prior written approval of such third party and Sponsor.

1. SUBJECT CONFIDENTIALITY, DATA PROTECTION

## This section applies to the Parties’ processing of Personal Data in the context of the Services. All capitalized terms used in this section unless specifically defined herein, shall have the meaning as set out in Regulation (EU) 2016/679 (“GDPR”).

## Personal Data may be processed in the context of Pharmacy’s performance of the Services, and certain Personal Data may be transferred between the Parties for the purposes of fulfilling this Agreement. The Parties agree to comply with all applicable laws and regulations regarding Study subject confidentiality and data protection, including the GDPR and the Norwegian Personal Data Act including any other legislation implementing the GDPR (“Privacy Legislation”).

## The Parties acknowledge that Pharmacy is a Controller when Personal Data are processed in the context of ordinary pharmacy specific activities as prescribed by law. Pharmacy specific activities include, but are not limited to (i) fulfilling documentation requirements; (ii) distribution of Study Drugs; and (iii) the preparation and/or compounding of Study Drugs. Sponsor is the Controller when Sponsor determines the purposes and means of the processing, including but not limited to situations where Personal Data are used (i) in Sponsor’s own information systems; (ii) for the purposes of fulfilling obligations attributed to Sponsor under applicable law (e.g. legislation on clinical trials); and (iii) for providing access to information systems to Pharmacy personnel. Hence, both Parties may be Controllers for the purposes of this Agreement.

## Each Party is responsible for fulfilling the obligations imposed on Controllers under the Privacy Legislation for the processing of Personal Data where the respective Party is considered a Controller, including with respect to establishing a legal basis for the processing.

## The Parties agrees to maintain appropriate measures to ensure the confidentiality and security of the Personal Data, and enter into all reasonable undertakings in respect to safeguard the fundamental rights and the interests of the Data Subjects in accordance with the Privacy Legislation. This includes implementing appropriate technical and organizational measures, executing data processing agreements and/or international transfer agreements whenever necessary, and safeguarding any obligations to notify to the supervisory authorities and to respond to requests for exercising the data subject's rights laid down in the Privacy Legislation. Hereunder, Sponsor ensures that study data shall not be available to anyone outside the EU/EEA. Should study data be made available to any entity outside the EU/EEA, Sponsor warrants that sufficient guarantees will be provided, including organizational and technical measurements (such as, but not limited to Standard Contractual Clauses (SCC)), so that further processing of data will be in accordance with the Data Protection Legislation.

## Pharmacy shall promptly inform Sponsor about any Personal Data Breach concerning Personal Data processed in the course of providing Services under this Agreement, including the timing and nature of the Personal Data Breach.

## Each Party shall notify the other of circumstances which may be of relevance to the other Party’s rights and obligations under the Privacy Legislation, including with respect to Data Subject requests where a Party considers that the other Party is responsible for handling such request. Each Party shall provide necessary information to the other, to the extent this is required for the Receiving Party to fulfill its obligations under the Privacy Legislation.

1. Intellectual Property

## All data, information and documents provided to the Pharmacy or the Principal Investigator by or on behalf of Sponsor, shall remain the sole property of Sponsor. The Pharmacy will respect all intellectual property rights, including patent, brand, design and copyrights of Sponsor or third party, likewise, Sponsor will respect all intellectual property rights, including patent, brand, design and copyrights of Pharmacy.

## All data, information and results that are collected in writing during the course of the Study and within the scope and regulations of the Protocol, and paragraph 4.5 in the GCP, including unexpected findings, unforeseen events or results that arise from deviations from the Protocol (the “Results”), shall be the sole property of Sponsor and may be used and/or transferred by Sponsor in its sole discretion with no further payment or other obligation to the Pharmacy, except as regulated in this Agreement.

## Pharmacy may continue to use any know-how gained during the performance of the Study for internal, non-commercial research purposes, provided that such use is made in accordance with the confidentiality provisions and subject to the intellectual property rights of Sponsor under this Agreement, and, provided that such right shall not extend to any know-how which is exclusively related to the Study Drug as such.

## In the rare event that a Pharmacy-employee is a named inventor on a patent/patent application arising from work performed under the study and according to protocol, and this is the basis of an extraordinary commercial success for Sponsor, the employee(s) may be able to claim a minor remuneration from the Pharmacy under the Norwegian law on Employee inventorship (or a succeeding law). If the employee raises any such claim against Pharmacy, Pharmacy shall inform Sponsor immediately and Sponsor and the Pharmacy shall jointly decide on how to handle the matter, provided that any compensation to be paid by the Pharmacy under such claim following a court decision or a settlement shall be reimbursed by Sponsor.

## The Pharmacy agrees to, and to cause its employees and collaborators to, execute promptly all documents and take all other action as may reasonably be requested by Sponsor to ensure that all Results are vested in or assigned to Sponsor in accordance with this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all Results to Sponsor in accordance with this Agreement, and at Pharmacy’s discretion assisting Sponsor in the preparation and prosecution of patent applications at Sponsor’ expense.

## The Pharmacy shall ensure that the Pharmacy’s employees and collaborators involved in the Study will comply with its obligations under this Agreement.

1. PUBLICITY

## Pharmacy will not disclose the terms of this Agreement or use Sponsor’s name, trademark, service mark or logo in any publicity, advertising or announcement, without Sponsor’s prior written consent.

1. PublicationS and PRESENTATIONS

## Pharmacy will not present or publish, or submit for publication, any work resulting from the Services under the Agreement without Sponsor’s prior written approval, such approval not to be unreasonably withheld.

1. Insurance and Indemnity

## Sponsor agrees to indemnify Pharmacy and hold Pharmacy harmless in respect of and against all claims and proceedings made or brought by or on behalf of Subjects against Pharmacy for personal injury to Subjects, including death, to the extent arising out of or relating to the administration of investigational medicinal product in accordance with this Agreement, the Protocol and any other written instructions of Sponsor, provided that:

* + - Pharmacy have followed the instructions of Sponsor and complied with the Protocol (and any amendments thereto) and applicable laws and requirements;

## Sponsor’s obligation to indemnify under Article 13.1 will not apply to the extent that such claims or proceedings:

* + - arise out of or relate to the gross negligence, willful misconduct or wrongful act or omission of Pharmacy staff;
    - arise out of or relate to Pharmacy’s failure to report promptly to Sponsor any significant or alarming development that has occurred during the Study; or
    - arise as a result of Pharmacy’s compromise or settlement of any such claim without the written consent of Sponsor.

## Sponsor maintains liability insurance in respect of its obligations to third parties and maintains sufficient limits to cover the indemnification obligations in this Agreement.

## Sponsor will take responsibility and provide compensation for Subject injuries in accordance with applicable laws and requirements, in particular the Norwegian Product Liability Act. In accordance with this act, Sponsor will obtain a special insurance, in the Norwegian Drug Liability Assurance Committee (*Legemiddelansvarsforeningen*), which will indemnify any injured persons in connection with the Study on a no-fault basis, that is, regardless of culpability.

## Any claim against Pharmacy for breach of contract cannot exceed the Agreement’s total amount, unless this is due to gross negligence of Pharmacy and this has been established either i) by agreement between the Parties or ii) by a final and enforceable judgement.

## The Pharmacy agrees to maintain insurance according to applicable laws and regulations.

1. Term and Termination

## This Agreement shall be effective upon full execution by the Parties, and shall terminate on the later of: i) one (1) year from its execution, or ii) the date of Study database lock if there is subject enrolment under this Agreement in the Study, or iii) the date of completion of all of the obligations of the Parties hereunder, unless terminated earlier as provided in below:

## Pharmacy will deliver all documents regarding its Services under this Agreement to the Investigator for archiving in the site file, following Sponsor’s/CRO’s final monitoring of the documents at Pharmacy. Pharmacy will keep a copy of the documents if deemed necessary for their internal documentation requirements.

## Either Party may request a re-negotiation of this Agreement due to for instance significant regulatory changes or unforeseen changes in costs or workload.

## Either Party may terminate this Agreement immediately upon written notice delivered to the other Party if the other Party is in breach of any obligations under the Agreement or the Protocol and fails to remedy such breach, where it is capable of cure, within fifteen (15) days of written notice from the other Party specifying the breach and requiring its cure;

## Sponsor may immediately terminate this Agreement upon delivering written notice to Pharmacy if, at any time during this Agreement, (i) Pharmacy loses its authorization, qualification or permit to act as Pharmacy under applicable laws; (ii) if insolvency was declared with respect to any of the Parties; or (iii) without cause upon thirty (30) days prior written notice to Pharmacy.

1. IndependenCe

## Pharmacy’s relationship to Sponsor under this Agreement is that of independent contractors and Pharmacy has no authority to bind or act on behalf of Sponsor.

1. Assignment

## Neither Party shall assign this Agreement or any of its, his or her rights or obligations hereunder without the prior written consent of the other Party, except that each Party may assign this Agreement and its rights and obligations hereunder to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates.

## Any permitted assignee shall assume all obligations of Pharmacy under this Agreement. Assignment shall not relieve Pharmacy of responsibility for the performance of any accrued obligation. Further, in the event that Pharmacy is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement obligating such subcontractor to comply with the terms and conditions hereof, and Pharmacy shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Pharmacy.

## Notwithstanding the foregoing, Sponsor may assign this Agreement and its rights and obligations hereunder (a) in connection with the transfer, whether by license or otherwise, or sale of all or substantially all of its rights to the Study Drug, (b) to any of its affiliates, or (c) to any external service providers such as contract research organizations retained to assist Sponsor in managing and monitoring the Study. Sponsor shall have the right to perform any and all of its obligations and exercise any of its rights under this Agreement through any of its affiliates.

1. Survival

## Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of this Agreement, shall remain in full force and effect.

1. Entire Agreement and Amendment

## This Agreement together with the Appendices hereto and, if applicable, the Confidentiality Agreement, constitute the entire agreement among the Parties hereto with respect to the subject matter of this Agreement and supersede all prior agreements, whether written or oral, with respect to the subject matter of this Agreement.

## Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each Party.

1. FORCE MAJEURE

No Party shall be liable to any other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance (a “**Delay**”) and when they cease to do so. In the event of a Delay lasting for four (4) weeks or more the non-affected Parties shall have the right to terminate this Agreement immediately by notice in writing to the other Parties.

1. DEBARMENT

The Pharmacy represents and warrants to the best of its knowledge that none of its employees, agents or other persons performing the Study under its direction, have been debarred, disqualified, convicted of a criminal offense related to the provision of any healthcare items or services, or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and Pharmacy shall notify Sponsor immediately if any such investigation, disqualification, debarment, conviction or ban occurs. Pharmacy represents that all of its employees, agents or other persons who will be involved in performing the Study are appropriately trained, qualified and certified, and are informed of their obligations under this Agreement and are bound by obligations to the Pharmacy to abide by the requirements of this Agreement.

1. ANTI-BRIBERY/ANTI-CORRUPTION

## The Pharmacy certifies that it shall not use its powers or its real or potential influence to improperly or unlawfully influence a decision, an act, an action or an omission with respect to the activities of Sponsor.

## In the event of a conflict of interest or the risk of a conflict of interest, Pharmacy agrees to not improperly or unlawfully participate in any duties or tasks of any official position held when the duty or task relates to the activities of Sponsor under this Agreement.

1. The Pharmacy certifies that it shall not offer or provide any payment, gift or anything of value, either directly or indirectly, to any government official, including, but not limited to, public officials, agents or employees of a public administration, persons acting on behalf of any of the foregoing, or any person responsible for a mission of public services or an elected office, representatives of any political party, candidates for public office, representatives of other businesses or persons acting on behalf of any of the foregoing, for the purpose of improperly or unlawfully influencing decisions, acts or omissions, with respect to the activities of Sponsor.
2. Governing Law and jurisdiction

## This Agreement shall be governed by and construed in accordance with substantive laws of Norway, with the exclusion of the conflict of law rules. The parties herby submit to the exclusive jurisdiction of the Oslo City Court (Oslo Tingrett).

1. Counterparts

## This Agreement is executed in two counterpart copies, each of which shall be deemed an original, and shall together be deemed to constitute one and the same instrument when signed by the authorized representatives of Sponsor and Pharmacy as of the dates indicated below. Each Party acknowledges that an original signature or a copy thereof transmitted by PDF shall constitute an original signature for purpose of this Agreement. Further, if signed electronically, the Parties acknowledge that the copies executed electronically and received by each Party shall constitute originals. The date of execution of this Agreement shall be the date of the last signature.

|  |  |
| --- | --- |
| SponSOR Date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [Name] [Title] | PHARMACY Date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [Name]  Head of Pharmacy |
|  |  |
| Read and Acknowledged; Date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [Name]  Principal Investigator |  |

Attachments:

* **Exhibit A** – Specification of *Services* and *Budget*

**EXHIBIT A**

**TO BE UPDATED BY PHARMACY FOR A GIVEN STUDY**

**Specification of *SERVICES* and *BUDGET***

**SERVICES**

Pharmacy shall provide the following Services relating to the Study and Study Drug in accordance with the terms of this Agreement:

* Receipt and control of Study Drug (e.g. damage/devaluation during shipment, batch numbers, expiration date, etc.), including registration/confirmation in IWRS
* Storage of Study Drug, including control of expiration date and storage conditions (temperature)
* Take all reasonable measures to ensure that Study Drug are kept secure, not used for any purpose other than the conduct of the Study, and not used past the labelled expiration date
* Dispensing of Study Drug, with full and accurate records of who dispenses, including proper documentation of preparation of Study Drug (e.g. preparation of infusions, etc.), the quantity dispensed, and the quantity returned
* On any termination of this Agreement, at Sponsor's expense, return any remaining quantities of the Study Drug to Sponsor, and document such return
* Destruction of Study Drug, following external or internal procedures
* Specific tasks and requirements in relation to this study:
  + INSERT TASK
  + INSERT TASK
  + INSERT TASK

|  |  |  |  |
| --- | --- | --- | --- |
| Number of patients planned at site: | | | |
| Planned first patient first visit: | | | |
| Planned last patient last visit: | | | |
| Study design: | | | |
| Double blind  Open | Randomized  Placebo controlled | Phase I  Phase II  Phase III  Phase IV | Pharmacy blinded  Pharmacy unblinded |

1. **Documents to be received at Pharmacy or agreed upon before first dispensing of Study Drug:**

|  |  |  |
| --- | --- | --- |
| Regulatory approval (NoMA) | IRB/EC approval (REK) | Protocol |
| Drug accountability log | MIA (Manufacturing and Importation Authorisation)  GDP certificate | WDA (Wholesale Distribution Authorisation)  GMP certificate |
| Prescription form/Requisition form | IWRS access | Instructions for preparation of Study Drug/pharmacy manual |

1. **Study Drug to be used and handled by the Pharmacy;**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Study Drug (Generic name) | Form | Strength | Vial / package size | Manufacturer | Commercial medication to be sold by Pharmacy |
| INSERT NAME OF Study Drug |  |  |  |  | No |
| INSERT NAME OF Study Drug |  |  |  |  | Yes |

1. **Use of biosimilars:**

|  |  |
| --- | --- |
| Not applicable | |
| Approved | Not approved |

1. **Storage condition:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Study Drug (Generic name) | Room temperature (15-25°C) | Cold (2-8°C) | Freezer (-15 - -25°C) | Ultra freezer (-25°C →) | Narcotic drug |
| INSERT NAME OF Study Drug |  |  |  |  |  |
| INSERT NAME OF Study Drug |  |  |  |  |  |
| INSERT NAME OF Study Drug |  |  |  |  |  |
| Commercial medication is to be stored as specified by manufacturer | | | | | |
|  | | | | | |

1. **Monitoring of temperature:**

|  |
| --- |
| Using Pharmacy normal routine |
| Using device/system supplied by the Sponsor, as described below |
| Procedure for temperature monitoring at the Pharmacy is as follows:  Pharmacy central system will register temperature continually and store data. Temperature logs will be printed monthly. The system will give an alarm if temperature is out of limit. |
| Other: |
|  |
| The storage conditions for all commercial drugs are monitored and documented using temperature recorders and routines as for Study Drug. |

1. **Equipment to be used and to be provided by sponsor:**

|  |
| --- |
| Not applicable |
| * INSERT EQUIPMENT |
| * INSERT EQUIPMENT |

1. **Equipment to be used and to be provided by the pharmacy:**

|  |
| --- |
| Not applicable |
| * INSERT EQUIPMENT |
| * INSERT EQUIPMENT |

1. **Shipments, ordering and receipt of Study Drug:**

|  |  |  |
| --- | --- | --- |
| Study Drug are shipped from Sponsor/Sponsor’s representative INSERT COMPANY NAME, ADDRESS AND COUNTRY: | | |
| Study Drug to be delivered at the following address: INSERT NAME OF PHARMACY, ADDRESS AND COUNTRY  NB: ONLY INSERT NAME OF PHARMACY ON PROFORMA INVOICE, DO NOT INCLUDE NAME/ADDRESS OF SITE | | |
| All at initiation of the study | Continuous during the study | After ordering by the  Pharmacy or Investigator |
| * **Routine for ordering of Study Drug:** | | |
| Automatically sent by Sponsor | Order by the Pharmacy | Order by Investigator/study nurse |
| In studies where the Pharmacy does not procure the Study Drug from commercial stock, Sponsor is responsible for the stock of Study Drug at site, including the amount, the expiry date and the quality | | |
| * **Routine for confirmation of receipt of Study Drug:** | | |
| E-mail E-mail address: | | |
| Fax Fax number: | | |
| IWRS IWRS web address: | | |
|  | | |
| Sponsor will provide access to IWRS for the following named Pharmacy staff working with the study:   * INSERT NAME * INSERT NAME | | |
| * **Documentation that must be provided to the pharmacy:** | | |
| Packing list/order | Proforma Invoice | Batch certificate/QP-release/Certificate of Conformity (CoC) |
| Temperature monitoring | IWRS work sheet |  |
|  | | |
| Study Drug will not be registered as received for usage until these documents have been provided and accepted | | |
|  |  |  |
| * **Packing material:** | | |
| To be returned to Sponsor | To be disposed of by the Pharmacy | |

1. **Import:**

|  |
| --- |
| **Import of Study Drug by  Sponsor** (see section 2.4 in the Pharmacy Agreement) |
| **Import of Study Drug by Pharmacy:** INSERT NAME OF STUDY DRUG(S) (see section 2.5 in the Pharmacy Agreement) |

1. **Dispensing:**

|  |  |  |  |
| --- | --- | --- | --- |
| * Prescriptions/requisitions for INSERT NAME OF STUDY DRUG(S) to be delivered to Pharmacy by: | | | |
| Personal delivery | CMS | E-mail | Post |
| Fax | IWRS information included | Other; | |
| * Method for delivery of Study Drug : | | | |
| Collected by staff from the ward / hospital | To be sent to ward | Collected by patient | To be sent to patient |
| Other; | | | |
| * Logs and/or forms to be filled in at dispensing: | | | |
| Drug Inventory Log | | Log to be provided by Sponsor  Log to be provided by the Pharmacy  Overview in IWRS sufficient | |
| Drug Dispensing Log (per patient) | | Log to be provided by Sponsor  Log to be provided by the Pharmacy  Overview in IWRS sufficient | |
| Requisition form/prescription form (to be provided by Pharmacy | | | |
| * Study Drug allocation: | | | |
| To each patient via IWRS by Pharmacy or Investigator  According to Study Drug/kit/component ID-number | | From a stock in common for all patients  According to randomized dose | |

1. **Labeling:**

|  |  |
| --- | --- |
| Study Drug to be labelled according to Norwegian regulation.   * The Pharmacy should label the study drug with following information: | |
| Drug fully labelled, nothing to be added by Pharmacy | |
| CMS/production label; adjusted to cover study requirements | |
| Randomization number/Patient number | Patient initials |
| Patient full name | Investigators name |
| Dispensing date | “For clinical trial use” |
| Dosing instruction | Other, please specify; |
| Re-labelling in case of extension of expiry date:  Norwegian Health Authorities have decided that a special production license is required to perform this task. Sponsor must perform any re-labelling unless pharmacy has acquired such license. Re-labelling performed by sponsor must be accompanied by a certificate of QP-release issued by the manufacturer | |

1. **Preparation of infusion bags:**

|  |  |  |
| --- | --- | --- |
| * Preparation of infusions with Study Drug: INSERT NAME OF STUDY DRUG(S) are to be done by: | | |
| Pharmacy | Hospital ward | Not applicable |
| * Preparation procedure: | | |
| CMS production | Work sheet provided by Pharmacy | |
| Lab work sheet to be approved by Sponsor before use | | |
| * Pharmacy shall prepare: | | |
| Infusion bag | Syringe | Other; |

1. **Return of dispensed Study Drug:**

|  |  |  |
| --- | --- | --- |
| Return of INSERT NAME OF STUDY DRUG(S) | | |
| From patient to Investigator | From Investigator to Pharmacy | From patient to Pharmacy |
| * Returned Study Drug to be counted and logged by: | | |
| Investigator /study nurse | Pharmacy | Returned medication stored at Pharmacy, involves no counting or logging |

1. **Destruction and export of Study Drug:**

|  |  |
| --- | --- |
| * Destruction of Study Drug to be done by: | |
| Sponsor | |
| Unused Study Drug: INSERT NAME OF STUDY DRUG(S) IF APPLICABLE    Used Study Drug (empty and partially used): INSERT NAME OF STUDY DRUG(S) IF APPLICABLE | Prepared by monitor and sent to Sponsor  Prepared by monitor and sent to third party; INSERT NAME OF COMPANY  Prepared by Pharmacy and sent to Sponsor  Prepared by Pharmacy and sent to third party; INSERT NAME OF COMPANY  Export by Pharmacy (see section 2.6 of the Pharmacy Agreement) |
| Pharmacy |  |
| Unused Study Drug: INSERT NAME OF STUDY DRUG(S) IF APPLICABLE | At the Pharmacy, in containers for hazard waste, documentation in destruction form.  At the wholesaler distributor’s location, documentation in destruction form.  At the wholesaler distributor’s location, documentation in destruction form and issuing destruction certificate.  Other, please specify: |
| Dispensed used Study Drug (empty and partially used): INSERT NAME OF STUDY DRUG(S) IF APPLICABLE | At the Pharmacy, in containers for hazard waste, documentation in destruction form.  At the wholesaler distributor’s location, documentation in destruction form.  At the wholesaler distributor’s location, documentation in destruction form and issuing destruction certificate.  Other, please specify: |
| Used Study Drug from production(empty and partially used): INSERT NAME OF STUDY DRUG(S) IF APPLICABLE | To be destroyed at the end of each workday at the Pharmacy. Will be sent for incineration in containers for hazard waste.  Other, please specify: |
| Destruction will only take place as agreed with Sponsor and be according to guidelines outlined by Sponsor | |

1. **Storage of randomization envelopes:**

|  |  |  |
| --- | --- | --- |
| Not applicable | | |
| * To be stored by: |  |  |
| Pharmacy | Investigator | Sponsor |

**Appendix 1,** **BUDGET TO BE UPDATED BY PHARMACY FOR A GIVEN STUDY**

The following prices have been agreed at the date of execution of this Agreement, for Services provided by the Pharmacy according to this Exhibit A. Pharmacy releases an updated price list annually, and the prices in this Exhibit A will be adjusted accordingly. The adjusted prices will apply from the date of the updated price list and to Services delivered from that date.

|  |  |  |
| --- | --- | --- |
| **Procedure / task** | | **Price in NOK** |
| Study start-up fee (preparations for start of the study at the Pharmacy, internal training, procedures, etc.) per study | |  |
| Pharmacy Import start-up fee (preparation for import, requesting and control of documentation, etc.), per study | |  |
| Monitoring visits and administration, price per month | |  |
| Storage of Study Drug:  Room temperature */* Cold Storage */* Freezer  A-substances */* B-substances | | - per shelfmeter per Study Drug per month |
| Manual ordering of Study Drug, per order | |  |
| Receipt, documentation and control of Study Drug, including registration in IWRS and disposal of packaging materials | | - per shipment |
| Import; Obtain and control of batch documents and other controls related to import | | - per shipment |
| Return of temperature tracking equipment and/or packing materials | | - per shipment |
| Dispensing of Study Drug, per patient per visit | |  |
|  | |  |
| Return of Study Drug from patient/ward:  without counting  including counting  including calculation of compliance | | - per return  - per unit/kit  - per unit/kit to each patient |
| Use of interactive system (IWRS) at dispensing/at return/at production | | - per dispensing / return / production (addition in price for production and dispensing) |
| Return for destruction and destruction locally | Export of Study Drug for destruction, accountability and documentation by Pharmacy  Destruction locally or through domestic third party, accountability and documentation by Pharmacy, per hour  Accountability, documentation, packing and shipping done by Sponsor | – Per shipment (Postage/shipping expenses are added. (including VAT))  Invoiced per hour according to current hourly fee  Free of charge |
| Preparation of Study Drug, per production | Standard preparation: *<Study Drug>*  Complicated preparation: *<Study Drug>*  Documentation  Cancellation fee  Sterile disposables and liquids for dissolving or infusion of Study Drugs | Priced according to current retail price at time of purchase. May vary during the course of the study |
| Audit/Inspection/extraordinary monitoring visits (including preparations) | | Invoiced per hour according to current hourly fee |
| Immediate expenses, for example at customs clearance, shipping costs, VAT at Study Drug import to Norway | | Amount invoiced to sponsor |
| Shipping/transport (incl. transport to patient) | | Invoiced per hour according to current hourly fee.  Postage/shipping expenses are added (including VAT).  Packing material and temperature logs will be invoiced |
| Other tasks, upon sponsors approval | | Invoiced per hour according to current hourly fee |
| Re-labeling of extended expiry date, per batch number per relabeling | | Invoiced per hour according to current hourly fee |
| Extra workload due to drug supply shortages | | Invoiced per hour according to current hourly fee |
| Extra workload due to unplanned Interactive system (IWRS) downtime | | Invoiced per hour according to current hourly fee |
| Medication to be provided by local pharmacy: | | Priced according to current retail price at time of purchase including VAT. May vary during the course of the study |
| Current hourly fee *<xxxx NOK>* | |  |

**Payment details:**

The Pharmacy shall prepare the invoice monthly (CMS production will always be invoiced monthly)  or quarterly

The Pharmacy shall **address** invoices to:

|  |  |  |
| --- | --- | --- |
| Sponsor name | (Sponsor, CRO or both?) | |
| Contact person for invoicing | Attention of: (Name) | |
| Address |  | |
| Zip / City |  |  |
| Country |  | |
| Org- number |  | |
| Sponsor reference | ***[FULL STUDY CODE]***  ***Study reference number***  ***Purchase order number (PO-number1)***  ***Other information to be specified on invoice*** | |

1 PO-number is, if applicable, to be provided by Sponsor before start of project. Must be valid for entire study or for a longer period of time.

The Pharmacy shall **send** invoices to:

|  |  |
| --- | --- |
| Sponsor / CRO e-mail for invoices |  |
| Contact person |  |

OR to the following address:

|  |  |  |
| --- | --- | --- |
| CRO / Sponsor name |  | |
| Contact person for invoicing |  | |
| Address |  | |
| Zip / City |  |  |
| Country |  | |

Sponsor shall make payments with the following terms of receipt of an invoice from the Pharmacy which meets all requirements according to Norwegian VAT and accounting legislation to the following account of the Pharmacy:

|  |  |  |
| --- | --- | --- |
| Invoicing name | Sykehusapotekene HF – Apoteknummer | |
| Invoicing address | c/o Helse Sør-Øst RHF  Postboks 404 | |
| Zip / City | N-2303 | Hamar |
| Country | Norway | |
| E-mail |  | |
| VAT/Org- number | 992 281 618 | |
| IBAN | NO2686017267789 | |
| BIC/SWIFT | DABANO22 | |
| Currency | NOK | |
| Account number (11 digit) | 8601 72 67789 | |
| Name of Bank | Danske Bank | |
| Payment terms | 30 days | |

Sponsor retains the right to require the Payee to submit proper and audit worthy itemization and documentation for any or all of the Pharmacy’s submitted invoices at any time. All payments are listed exclusive of taxes. If any taxes apply, payee will add these to invoices, to be paid by Sponsor. The Pharmacy retains the right to send invoices per email or regular mail.

Pharmacy acknowledges and agrees that the payments made by Sponsor under this Agreement represent Sponsor’s total obligations.

Any expenses not specified in the Agreement or changes to the budget should be communicated to and approved in advance and in writing by Sponsor.