**MASTER PHARMACY AGREEMENT**

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

1. [SPONSOR], located at [address]  (**Sponsor**), and
2. Hospital Pharmacies Enterprise South-Eastern Norway (*Sykehusapotekene HF*, Org.no. 992 281 618), Stenersgaten 1A, 0050 Oslo, Norway (**SAHF**)

**BACKGROUND**

1. WHEREAS, SAHF is a hospital pharmacy enterprise owned by the South-Eastern Norway Regional Health Authority (“**HSØ**”), managing the hospital pharmacies in HSØ, and being responsible for this Agreement on behalf of these pharmacies.
2. WHEREAS, Pharmacy is a hospital pharmacy within SAHF and located at a hospital in HSØ, as specified in the Work Order, and providing the Services listed in the Work Order. A Work Order must be specified for each Pharmacy involved in a clinical study.
3. WHEREAS, This Agreement offers the parties a framework for pharmacy services to be performed by Pharmacy in relation to a given clinical study (**Study**) performed by Sponsor at any given hospital in HSØ (**Institution**), by issuance of specifications for the Study in the attached **Work Order** template. The performance of the Study at Institution is regulated in a separate clinical trial agreement.
4. WHEREAS, The specific details for each study shall be separately negotiated and specified in writing in a Work Order. The Work Order shall be executed by an authorized representative of Sponsor, Pharmacy and the applicable Principal Investigator.
5. WHEREAS, Each Work Order will include specifications of the tasks to be provided by the Pharmacy (**Services**). The Protocol shall be provided separately for each individual study and referred to and incorporated by reference in each Work Order. Each Work Order shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Work Order.
6. WHEREAS, Sponsor is sponsor of the Study as defined in the Work Order.
7. WHEREAS, Inven2 AS, located at Forskningsparken, Gaustadalléen 21, 0349 Oslo, Norway, is authorized to negotiate the Agreement on behalf of SAHF.
8. WHEREAS, The negotiation of payments/compensation for the performance of the Services by the Pharmacy, to be specified in the Work Order, is handled directly between the Sponsor and the Pharmacy.
9. COMPLIANCE WITH LAW

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

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

## The Sponsor shall provide Pharmacy with sufficient quantity of the Investigational Medicinal Products (Study Drug (IMP)). 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. Sponsor will assist Pharmacy in maintaining the equipment in good working order at Sponsors expense. All such equipment shall be listed in the Work Order 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 Work Order to this Agreement); Sponsor must ensure that all relevant documents are in order and that Sponsor is recognized as the importer in any Study Drug import documents regarding the study. Sponsor must present necessary documentation to the Pharmacy of Sponsor’s or Sponsor’s representatives’ authorization for such import.

## Import by Pharmacy: If Pharmacy is responsible for the import of Study Drug (ref Work Order 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 Authorization (WDA) and GDP certificate) or from an approved manufacturer (with Manufacturing and importations Authorization (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).

## Sponsor assumes all financial responsibility for any damage that would happen to goods and/or 3rd parties or receiver in conjunction with the shipping of the Study Drug (IMP). The Pharmacy will not be held responsible for any damage that may occur.

## 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 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 NoMA approval for this Protocol.

## 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 Importer of record on shipment documents.

## *Export*: If Pharmacy is responsible for the export of Study Drug for return and/or destruction (ref Work Order 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 Authorization (WDA) and GDP certificate) or from an approved manufacturer (with Manufacturing and Importations Authorization (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 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 temperature surveillance is needed during transport, Sponsor is responsible for providing necessary equipment such as temperature loggers and packing material.

## Sponsor assumes all financial responsibility for any damage that would happen to goods and/or 3rd parties or receiver in conjunction with the shipping of the Study Drug (IMP). The Pharmacy will not be held responsible for any damage that may occur.

## 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 the Norwegian Medicines Agency (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 in accordance with applicable laws and regulations, and that Pharmacy has approved/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 Work Order.

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

1. MONITORING AND ACCESS

## SAHF shall ensure that Pharmacy, during the Study, permits 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 and the applicable Work Order, Sponsor shall pay Pharmacy as per Appendix 1 to the Work Order. Prices for the Services as defined in the Work Order will be calculated based on the current price list from SAHF. 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.

## 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 Appendix 1 to the Work Order.

## SAHF 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 SAHF nor Pharmacy Staff have received any other compensation or inducement in connection with this Agreement or their participation in the Study.

## SAHF 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 a 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.

## Any start-up fee will be invoiced upon signing of any Work Order. This fee is a one-time compensation for work performed by Pharmacy in the planning and preparation phase of any 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 a Study at the Institution.

1. CONFIDENTIALITY

## During the Term (as defined below) of this Agreement and for ten (10) years thereafter, a Party and its employees, agents, subcontractors and affiliates (collectively the “Receiving Party”) shall not disclose Confidential Information it has received from the other Party (“disclosing Party”) without disclosing Party’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 disclosing Party’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 disclosing Party’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 disclosing Party prompt written notice (and in any case at least five (5) business days’ notice), to the extent permitted by law or regulation, to allow disclosing Party to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or disclosing Party waives compliance with the terms of this Section 7, Receiving Party shall furnish only that portion of the Confidential Information which is legally required based on the written opinion of legal counsel.

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

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 the Controller when Personal Data are processed in the context of pharmacy specific activities. Pharmacy specific activities include, but are not limited to (i) fulfilling documentation requirements as prescribed by law; (ii) distribution of Study Drugs; and (iii) the compounding of Study Drugs and/or ordering of infusions. 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.

## 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.

## 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.

## Depending on the Services Pharmacy performs, Pharmacy may be required to collect, retain, disclose or otherwise process Personal Data on Sponsor’s instructions and for purposes Sponsor has determined. If Pharmacy shall carry out such activities on behalf of Sponsor, the Parties shall enter into the Data Processor Agreement attached as Appendix 2 to this Agreement where Pharmacy by delegation from Sykehusapotekene HF shall be regarded as a Processor, and Sponsor shall be regarded as the Controller. The Data Processor Agreement shall clearly identify the processing operations for which Pharmacy is a Processor.

1. Intellectual Property

## All data, information and documents provided to SAHF or the Principal Investigator by or on behalf of Sponsor, shall remain the sole property of Sponsor. SAHF and the Principal Investigator 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.

## SAHF 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 SAHF -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 SAHF under the Norwegian law on Employee inventorship (or a succeeding law). If the employee raises any such claim against SAHF, SAHF shall inform Sponsor immediately and Sponsor and SAHF shall jointly decide on how to handle the matter, provided that any compensation to be paid by SAHF under such claim following a court decision or a settlement shall be reimbursed by Sponsor.

## SAHF 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 data, information, documents and inventions and Results to Sponsor in accordance with this Agreement, and assisting Sponsor in the preparation and prosecution of patent applications at Sponsor’ expense.

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

1. PUBLICITY

## SAHF 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

## SAHF 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 SAHF and hold SAHF harmless in respect of and against all claims and proceedings made or brought by or on behalf of Subjects against SAHF 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:

* + - SAHF 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 11.1 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 SAHF staff;
    - arise out of or relate to SAHF’s failure to report promptly to Sponsor any significant or alarming development that has occurred during the Study; or
    - arise as a result of SAHF’s compromise or settlement of any such claim without the written consent of Sponsor.

## Sponsor shall maintain 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, meaning regardless of culpability.

## Any claim against Pharmacy for breach of contract cannot exceed the Work Order’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.

## SAHF agrees to maintain insurance according to applicable laws and regulations.

1. Term and Termination

## Subject to subparagraphs 11.4 and 11.5 below, this Agreement shall be effective upon its full execution Agreement and for a duration of three years. Unless one of the parties has given written notice to the other party at least three months before its expiration, the Agreement shall be automatically renewed for a new three year period, unless terminated earlier as provided below. The Agreement shall expire automatically at the end of the renewal period.

## Pharmacy will deliver all documents regarding its Services under this Agreement to the Principal 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.

## 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; or

## Sponsor may immediately terminate this Agreement upon delivering written notice to SAHF if, at any time during this Agreement, (i) SAHF looses its authorization, qualification or permit to act as SAHF 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 SAHF.

1. IndependenCe

## SAHF’s relationship to Sponsor under this Agreement is that of independent contractors and SAHF 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 SAHF under this Agreement. Assignment shall not relieve SAHF of responsibility for the performance of any accrued obligation. Further, in the event that SAHF 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 SAHF shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by SAHF.

## 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 neither it, nor any of its employees, agents or other persons performing the Study under its direction, has 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 Site 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 SAHF 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.

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| --- | --- |
| SponSOR Date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [Name] [Title] | SAHF Date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Tore Prestegard  CEO |
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**Attachments:**  *Work Order* template

**WORK ORDER**

**To MASTER PHARMACY AGREEMENT**

For Protocol No. XXXXXXXXX entitled “XXXXXXXXXXXXXXXXXXXX” (“**Study**”)

This Work Order, issued under the Master Pharmacy Agreement effective DDMMMYYYY (**Agreement**), is entered into by and between

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

The Agreement is entered into by Sponsor and Hospital Pharmacies Enterprise, South-Eastern Norway (“**SAHF**”). Pharmacy is a division of SAHF.

This Work Order includes the terms and conditions of the Agreement, which are hereby incorporated herein by this reference.

In the event the Agreement has expired or been terminated under the duration of this Work Order, the terms and conditions of the Agreement shall continue to apply for this Work Order.

Institution and Principal Investigator (as listed in section 1. below) will conduct the Study in strict adherence to the Protocol.

The Investigational Product(s) for this Study, XXXXXXXXXXX (“**Study Drug**”), will be handled by the Pharmacy according to specifications in this Work Order.

Pharmacy shall provide Services (as defined below) relating to the Study and Study Drug in accordance with the terms of this Work Order, by using Pharmacy personnel only and according to internal procedures at the Pharmacy.

1. **CONTACT PERSONS**

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:**  **E-mail:** | **If to Institution:**  **E-mail:** |
| **If to Sponsor:**  **E-mail:** | **If to Principal Investigator:**  **E-mail:** |
| **If to Inven2:**  Inven2 AS  Gaustadalléen 21  0349 Oslo, Norway  Att: Siri Kolle  **E-mail:** [post@inven2.com](mailto:post@inven2.com) | **If to Study nurse or any other relevant personnel:**  **E-mail:** |

1. **COMPENSATION**

In consideration for Pharmacy’s services hereunder, Sponsor shall pay the Pharmacy as per the Budget attached hereto as **Appendix 1** and in accordance with the terms of the Work Order. For studies exceeding 4 years duration, Pharmacy reserves the right to re-negotiate the prices.

1. **STUDY TERMINATION**

This Work Order shall be effective upon full execution by the parties (the Effective Date), and shall terminate on the later of: i) one (1) year from the Effective Date, or ii) the date of Study database lock if there is subject enrolment under this Work Order in the Study, or iii) the date of completion of all of the obligations of the parties hereunder, unless terminated earlier pursuant to the terms of the Master Pharmacy Agreement or this Work Order.

**5. 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.

**6. COUNTERPARTS**This Work Order 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, Pharmacy and Investigator 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 Work Order.

**7. ENTIRE AGREEMENT**This Work Order and the Agreement contain the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of conflict between the provisions of the Protocol and the terms and provisions of this Work Order or any exhibits or appendices hereto, the Protocol shall control with respect to matters of science, medical practice and safety of Study subjects. In all other matters the terms and provisions of this Work Order shall control. In the event of any conflict between the terms and provisions of this Work Order and those of the Agreement, the terms and provisions of the Agreement shall control, unless this Work Order specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this Work Order controls for this Work Order only. This Work Order may be modified only by written agreement signed by the parties to this Work Order.

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

Attachments to this Work Order:

* **Appendix 1** – Specification of *Services* and *Budget*
* **Appendix 2 –** Data Processor Agreement (“**DPA**”)

**APPENDIX 1 TO WORK ORDER TO BE UPDATED FOR EACH STUDY**

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

Pharmacy shall provide the following Services relating to the Study and Study Drug in accordance with the terms of this Work Order (**Services**):

* Receipt and control of study drug (e.g. damage/devaluation during shipment, batch numbers, expiration date, etc.), including registration/confirmation in IVRS/IWRS
* Import, if relevant, see section 2 in the Agreement and section for Import and Export below.
* 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 Work Order, at Sponsor's expense, return any remaining quantities of the Study Drugs to Sponsor, if possible, and document such return
* Destruction of study drugs, following external or internal procedures
* Specific tasks and requirements in relation to this study:
  + Xxxxxxxxxxx
  + Xxxxxxxxxxx
  + Xxxxxxxxxxx

|  |  |  |  |
| --- | --- | --- | --- |
| Number of patients planned at site: | | | |
| Planned First Patient in: | | | |
| Planned Last Patient out: | | | |
| Study design:  double blind  open | randomized  placebo controlled | Phase I  Phase II  Phase III  Phase IV | pharmacy blinded  pharmacy unblinded |

|  |  |  |
| --- | --- | --- |
| Documents to be received at Pharmacy or agreed upon at initiation / before first dispensing of study medication: | | |
| Regulatory approval (NoMA) | IRB/EC approval (REK) | Protocol |
| Work order | Prescription form | Drug accountability log |
| WDA (Wholesale Distribution Authorisation) | MIA (Manufacturing and Importation Authorisation) | Lab-procedure |
| Consent form approved by REK | IVRS / IWRS access | Copy of labels approved by NoMA |
| Copy of Study delegation log, including delegated Pharmacy tasks, authorised and signed by PI | |  |

**Study drugs and equipment to be used in this clinical study;**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name of study drug (Generic name) | Form | | Strength | Vial / package size | | Manufacturer | | | Commercial medication to be sold by Pharmacy |
|  |  | |  |  | |  | | | No |
|  |  | |  |  | |  | | | Yes |
| Following medication / equipment are to be used in the study and to be handled by the pharmacy: | | | | | | | | | |
| Medication (Study Drug): estimated storage need:      shelf meters (minimum 1 meter) | | | | | | | | | |
| Storage conditions: | |  | | | Monitoring of temperature: | | | | |
| Room temperature (15-25°C) | | Narcotic drug | | | Using Pharmacy normal routine | | | | |
| Cold (2-8°C) | |  | | | Using device supplied by the Sponsors | | | | |
| Freezer (-15 - -25°C)  Ultra freezer (-25°C →) | |  | | |  | |  |  | |
| Commercial medication (Product name): estimated storage need:      shelf meters (minimum 1 meter) is to be stored as specified by each manufacturer. | | | | | | | | | |
| 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.  Manual system, with max/min thermometers, recording every weekday except public holidays.  Other, describe:  The Sponsor will not supply any additional system for temperature monitoring for this study.  OR  The Sponsor will supply an additional system for temperature monitoring for this study, as follows:  - | | | | | | | | | |
| The storage conditions for all commercial drugs are monitored and documented using temperature recorders and routines as for study drug. | | | | | | | | | |
| **Equipment provided by sponsor:**   * xxxxxxx * xxxxxxx | | | | | | | | | |

**Shipments and receipt of study drug:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study medications are shipped from Sponsor’s representative (Company name, location address and country): | | | | |
| All at initiation | | Continuous | | After ordering |
| Routine for ordering of study medications: | | | | |
| Automatic | | By Pharmacy | | By Investigator / study nurse |
| In clinical studies where the Pharmacy does not procure the study drugs from commercial stock, the 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: | | | |
| IVRS | IVRS Telephone number: | | | |
| IWRS | IWRS / web address: | | | |
| Sponsor will provide access to IVRS/IWRS for named Pharmacy staff:  - | | | | |
| Documentation of receipt, must be checked and archived:  Packing list / order  Temperature monitoring  IVRS/IWRS work sheet  Batch certificate/QP-release/CoC | | | | |
| Packing material:  Return to sponsor | | | To be disposed of by pharmacy | |

**Import and Export:**

|  |
| --- |
| **Import by  Sponsor**  (see section 2.3 of the Master Pharmacy Agreement)  **Import by Pharmacy** Specify name of study drug(s)  (see section 2.4 of the Master Pharmacy Agreement)  **Export of Study Drug by Pharmacy**, for return to Sponsor and/or destruction  (see section 2.5 of the Master Pharmacy Agreement) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Dispensing:** | | | | | | |
| Prescription-/Requisition form:  A list of Investigator and co-investigators who can prescribe/requisition study medication for patients in this Study, must be provided to Pharmacy. This list may be amended during the Study. | | | | | | |
| Prescriptions/Requisitions for (Study Drug) and (Study Drug) to be delivered to Pharmacy by | | | | | | |
| Personal delivery | Cytodose®/CMS | | e-mail | | Post | Fax |
| IVRS / IWRS information included | | | Other: | | | |
|  | | | | | | |
| Delivery method:  Collected by staff from the ward / hospital  To be sent to ward  Collected by patient  To be sent to patient (Shipment is performed in accordance with the applicable SOP of the SAHF)  Other, specify: | | | | | | |
| Logs and / or forms to be filled in at dispensing: | | | | | | |
| Drug Inventory log  Drug Dispensing log (per patient)  Requisition form/ Prescription form | | | | Log to be provided by Sponsor  Log to be provided by Pharmacy  Log to be provided by Sponsor  Log to be provided by Pharmacy  Log to be provided by Sponsor  Log to be provided by Pharmacy | | |
| Study drug is allocated… : | | | | | | |
| …to each patient via IVRS / IWRS by Pharmacy OR Investigator | | …from a stock in common for all patients | | | | |
| …according to Medication ID-number | | …according to randomized dose | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Labeling:**  Study drugs to be labelled according to Norwegian regulations.  Drug fully labelled, nothing to be added by Pharmacy.  The Pharmacy must label the study drug with following information: | | | |
| Randomization number/Patient number | | Patient initials | Patient’s full name |
| Investigator’s name | Dispensing date | Cytodose/CMS label adjusted to cover study requirements | |
| Expiry time | Pharmacy production number = site tracking number | | |
| ”For clinical trial use” | Dosing instruction: | | |
| Other, 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. The 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. | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Preparation of infusion bags:** | | | | | | |
| Preparation of infusions with study drug (Study Drug 1) and (Study Drug 2) are to be done by : | | | | | | |
| NA | Pharmacy | | Hospital ward | | | |
| Laboratory work sheets must be made for every preparation.  Original work sheets to be archived in the study file; the Pharmacy may keep a copy. | | | | | | |
| Preparation procedures: | | | | | | |
| Cytotoxic drugs  Pharmacy will use Cytodose/CMS and make necessary preparations in this system | | | | Other work sheet | Lab work sheet to be approved by Sponsor before use | |
| Pharmacy shall prepare: | | | | | | |
| Infusion bag | | Syringe | | | | Other: |

**Return of dispensed study drug**

|  |  |  |
| --- | --- | --- |
| Return of study drug | | |
| From patient to Investigator | From Investigator to Pharmacy | From patient to Pharmacy |
| Returned medication to be counted and logged by: | | |
| Investigator /study nurse | Pharmacy |  |
| Returned medication stored at Pharmacy, involves no counting or logging | | |

|  |  |
| --- | --- |
| **Destruction and/or return to Sponsor:** | |
| Destruction of study drugs to be done by: | |
| Sponsor: | |
| * Unused study drugs: (Specify study drug/-s, if applicable) * Used study drugs (Empty and partially used): (Specify study drug/-s, if applicable) | Prepared by  Monitor/ Pharmacy  and sent to  Sponsor or to  (Name) for destruction according to guidelines outlined by Sponsor.  Export by pharmacy is necessary (see section 2.4 of the Master Pharmacy Agreement) |
| Pharmacy: |  |
| * Unused study drugs: (Specify study drug/-s, if applicable) | Pharmacy: According to the SAHF SOP.  Pharmacy: To be destroyed at the the Pharmacy lab. Will be sent for incineration with other cytotoxic waste from the hospital. Procedure documented in local SOP.  Other: (Describe procedure) |
| * Dispensed used study drugs (Empty and partially used): (Specify study drug/-s, if applicable) | Pharmacy: According to the SAHF SOP.  Pharmacy: To be destroyed at the Pharmacy lab. Will be sent for incineration with other cytotoxic waste from the hospital. Procedure documented in local SOP.  Other: (Describe procedure) |
| * Used study drugs from production (Empty and partially used): (Specify study drug/-s, if applicable) | Pharmacy: According to the SAHF SOP.  Pharmacy: Used (empty and partly used) vials of (Study Drug) and (Study Drug) to be destroyed at the end of each workday at the Pharmacy lab. Will be sent for incineration with other cytotoxic waste from the hospital. Procedure documented in local SOP.  Other: (Describe procedure) |
| Destruction will only take place as agreed with the Sponsor. | |

**Storage of randomization code envelopes** NA

|  |  |  |
| --- | --- | --- |
| 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, for Services provided by the Pharmacy according to this Work Order:

|  |  |  |
| --- | --- | --- |
| **Procedure / task** | | **Price in NOK** |
| Start-up fee (preparations for start of the study at the Pharmacy, internal training, procedures, etc.) per study | |  |
| Import-related costs (preparation for import, requesting and control of documentation, etc.) , per study | |  |
| Receipt and control of Study Drug, including registration in IVRS/IWRS and disposal of packaging materials, per shipment | |  |
| Manual ordering of Study Drug, per order | |  |
| Storage of Study Drug, Room temperature/Cold Storage/Freezer/Ultra freezer price per volume/shelfmeter per year | |  |
| Monitoring visits and administration, price per month | |  |
| Dispensing of Study Drug, per patient per visit……. | |  |
| Preparation of Study Drug, per unit per visit……. | |  |
| Per produced unit  Prescriptions for XX IV or placebo to be delivered/faxed to Pharmacy  through order form, prepared by the pharmacy | Preparation XX IV  Documentation per production/dispensing  Cancellation fee  Use of IWRS at dispensing/or return and/or production (per activity) (if applicable)  Sterile disposables for dissolving or infusion of study drug | NOK  NOK  NOK  NOK  Priced according to current retail price at time of purchase. May vary during the course of the study. |
| Cancellation fee, per unit | |  |
| Documentation, per unit | |  |
| Sterile disposables and liquids for dissolving or infusion of study drug | | Priced according to agreed price at time of purchase. May vary during the course of the study. |
| Return of Study Drug from site/patient, including registration, per patient per visit……. | |  |
| Immediate expenses, for example at customs clearance, shipping costs, VAT at import to Norway | |  |
| Destruction of partially used/unused study drugs, per hour | |  |
| Preparations for and work during an audit or inspection, set rate or per hour | |  |
| Audit/Inspection/extraordinary monitoring visits (including preparations) | | Is invoiced per hour according to the agreed hourly fee |
| Consulting/Other tasks | | Is invoiced per hour according to the agreed hourly fee |
| Transport to patient | | Is invoiced per hour according to the agreed hourly fee |

**Payment details:**

The Pharmacy shall prepare the invoice 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.

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 og navn | |
| Contact person for invoicing |  | |
| Invoicing address | c/o Azets Insight AS  Postboks 1552 | |
| Zip / City | N-7435 | Trondheim |
| 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.

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.

**Appendix 2 to WORK ORDER**

**TO BE CONSIDERED AND FILLED IN FOR EACH STUDY, WHEN APPLICABLE**

DATA PROCESSOR AGREEMENT

In accordance with the Personal Data Act (15.06.2018) and

EU General Data Protection Regulation 2016/679

between

**Sponsor**

*Controller*

and

**Pharmacy**

*Processor*

# Introduction

This Data Processor Agreement (hereinafter referred to as “the **DPA**”) regulates the rights and obligations between Controller and Processor (hereinafter referred to as “the Parties”) pursuant to:

* Act no. 38 of 15 June 2018 on the processing of personal data (the Personal Data Act) transposing Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the General Data Protection Regulation) (hereinafter referred to as “the GDPR”);
* Any law, regulation or other provisions that supersedes or supplies these.

Hereinafter referred to as “the Regulations”.

The purpose of the DPA is to ensure that the processing of personal data on behalf of Controller is carried out in accordance with applicable instructions and the requirements of the Regulations.

In the event of a discrepancy between the provisions of the Agreement and the Regulations, the provisions of the Regulations shall take precedence.

# Definitions

Terms and definitions used in the DPA shall be interpreted in the same manner as in the Personal Data Act and the GDPR.

# Scope

This DPA applies to the specific processing of Personal Data that Processor performs on the basis of the Work Order, on behalf of Controller, ref section 6.8 in the Agreement. The DPA only applies to the processing activities identified in **Annex 1** of this DPA.

In the event of a discrepancy between this DPA and the Agreement/Work Order, this DPA shall take precedence.

This DPA will also apply to further processing of personal data based on Work Orders between the parties entered into during the term of the Agreement that imply that Processor processes personal data on behalf of Controller. The information required under the DPA shall be filled in for each such Work Order and the DPA shall be attached as Appendix 2 to the Work Order.

# Purpose of the processing, data and processing

The purpose and duration of the processing of personal data, the personal data to be processed, categories of data subjects and the nature of the processing are specified stated in **Annex 1**.

# General rights and obligations of Controller

Controller shall at all times have full right of use of and authority to issue instructions relating to the personal data that Processor processes on behalf of Sponsor under this DPA. Processor may not process such data for its own purposes.

Unless otherwise agreed or enforced by law, Controller shall be entitled to access to the personal data processed by Processor.

Controller shall comply with the obligations laid down in the Regulations and this DPA.

# General obligations of Processor

Processor shall comply with the Regulations and only process personal data in accordance with the DPA and documented instructions issued by Controller, unless required by European Union law or national law applicable to Processor. In such a case, Processor shall notify Controller in writing of the aforementioned statutory requirements before processing is commenced, unless such notification is prohibited by law or public authority.

Processor shall not process personal data for other purposes, in any other way or to a greater extent than provided for in this DPA and as necessary in order to fulfil the Work Order.

Processor shall furthermore:

1. ensure that persons authorised to process personal data, and any processors, have received adequate training and are subject to a confidentiality obligation;
2. assist Controller in ensuring compliance with the obligations relating to the implementation of a satisfactory level of security in accordance with the GDPR Art. 32-36, taking into account the nature of the processing and the data that is available to Processor;
3. assist Controller by means of appropriate technical and organisational measures to fulfil the Controller’s obligation to respond to requests submitted by data subjects for the purpose of exercising rights under the Regulations;
4. make available to Controller any information necessary to demonstrate that Processor's obligations are fulfilled, and facilitate and contribute to audits, including inspections, which are conducted by Controller or another inspector with the authority of Controller;
5. notify Controller of Personal data breaches without undue delay in accordance with the GDPR Art. 33;
6. notify Controller immediately if Processor believes that any instructions are in breach of the GDPR or other provisions relating to personal data protection;
7. fulfil other obligations applicable to Processor pursuant to this DPA or the Regulations.

Processor shall document its procedures and all measures to meet the requirements of the DPA and the Regulations. This documentation shall be made available to Controller upon request.

If Processor is obliged by law or other exercising of official authority to personal data governed by this DPA in a manner other than that as specified in this DPA or documented instructions from Controller, Controller shall be notified in writing before the processing is commenced, unless this is prohibited on important grounds of public interest.

# Use of processors

Controller consents to the use of sub-processors as identified in **Annex 2**. Notification of planned change of sub-processors shall be made in writing at least 60 days prior to the change. Controller may consent in writing to the change taking effect before 60 days have passed. Processor shall ensure that sub-processors are subject to the same level of data protection obligations as required by this DPA and applicable Regulations. Processor is fully accountable to Controller for sub-processors’ compliance with the provisions of this DPA and the Regulations. Further requirements regarding the use of processors are stipulated in **Annex 2**.

# Transfer of personal data abroad

The parties to this DPA agree that no personal data processed under this DPA shall be transmitted out of Norway, unless specifically agreed between the parties; see **Annex 2**. Controller consents to such transfers abroad as specified in **Annex 2**. This also includes remote access from abroad.

In the event of transfer abroad, whether within the EU/EEA or outside the EU/EEA (third countries), Processor shall at the request of Controller provide the necessary documentation concerning the transfer, security, risk and level of compliance linked to the sub-processors concerned.

# Personal data breach

If a Personal data breach is suspected, Processor shall notify Controller without undue delay and within no more than 48 hours where this is feasible. The notification shall give a written account of the Personal data breach in accordance with the requirements of the GDPR Art. 33 (3). Controller shall furthermore document the actual circumstances related to the Personal data breach, its impact and any remedial action taken.

# Duty of confidentiality

Processor’s employees and others who act on Processor’s behalf in connection with the processing of personal data in accordance with this DPA shall be subject to a duty of confidentiality under this DPA and applicable regulations.

# Audits

In order to verify compliance with this DPA and the Regulations, Controller may conduct audits either itself or by using an independent third party which in this regard shall be bound by a duty of confidentiality with respect to any party other than Controller. Audits shall not normally be conducted more than once per year, unless otherwise provided for by the Agreement/Work Order. Any such audit shall comply with Processor’s reasonable security requirements and shall not unreasonably interfere with Processor's other activity.

Processor may require that documented additional costs in connection with such audits are covered by Controller. The foregoing shall not apply if serious breaches of this DPA or the Regulations are identified.

# Duration and termination

This DPA applies from the date the Work Order has been signed by the parties and is valid until the termination or expiration of the Work Order . However, the DPA shall be valid as long as Processor actually processes personal data on behalf of Controller.

Upon termination of the DPA, Processor shall facilitate and contribute to the return of all Processor has received and processed on behalf of Controller. The parties shall agree in more detail on how the transfer shall take place. Processor shall, upon request, give Controller written confirmation that the data has been transmitted and erased as stated above.

# Liability

The limitation of liability as set out in the Agreement/Work Order also applies to Processor’s liability for breaches of this DPA.

# Notices

Notices, information, notification or other communication between Controller and Processor shall be given in writing or confirmed in writing to:

|  |  |
| --- | --- |
| **Controller** | **Processor** |
| **[Name of enterprise]**  [Address] | **[Name of enterprise]**  [Address] |
| Name:  Role:  E-mail:  Mobile phone no.: | Name:  Role:  E-mail:  Mobile phone no.: |

# ANNEX 1 – Purpose of the processing, data and processing

The tables are updated continuously.

[*date/month/year*]

## The purpose and duration of the processing

The purpose and duration of processing data concerning personal data is: *[remember that each processing must be connected to specific and explicitly stated purposes – see the example below]*

|  |  |  |
| --- | --- | --- |
| **Name of service** | **The purpose of the processing** | **The duration of the processing** |
| [e.g storing specific study documentation containing personal data on behalf of Sponsor] |  |  |
|  |  |  |

## Processing data concerning personal data

The following processing is covered by the DPA: [list the relevant processing of personal data]

|  |  |
| --- | --- |
| **Processing** | **Processing activities** |
| Collection |  |
| Registration |  |
| Organisation |  |
| Structuring |  |
| Storage |  |
| Adaptation or alteration |  |
| Retrieval |  |
| Compilation |  |
| Erasure or destruction |  |
| Disclosure/Transfer |  |

## Types of information

The following data concerning personal data are processed: *[list here the data concerning health and personal data that is included – see examples below]*

|  |  |
| --- | --- |
| **Personal data** | **Data concerning health** |
| Name  National identity number  Address | Use of medicines  Diagnostic data  Data from health registries |

## Categories of data subjects

Data regarding the following categories of persons (data subjects) is processed: *[the categories of data subjects included are listed here – see the examples below]*

|  |  |  |
| --- | --- | --- |
| **Categories of data subjects** | | |
| [E.g. study subjects] |  |  |

# ANNEX 2 - Processors and transfers abroad

*[list here the processors used by Processor – see the examples below]*

The tables are updated continuously.

*[date/month/year]*

|  |  |  |
| --- | --- | --- |
| **Name of processors** | **Supply area** | **Location** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Controller has approved the following transfers abroad; see Article 9 of the DPA:

|  |  |
| --- | --- |
|  | **Description:** |
| 1. |  |
| 2. |  |
| (3). |  |

Processor shall keep the overview of the identity and location of processors and approved transfers abroad up to date. An updated list shall be made available to Controller upon request.