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| TITLE PAGE |
| USABILITY STUDY AGREEMENT between[COMPANY]and[HOSPITAL] HF and[PAYEE] |
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| --- | --- |
| Study Name: | […] |
| Protocol no: | […] |
| Study Site: | [Hospital, Department] |
| Project Leader: | […] |
| [Payee/Institution] reference no : | […] |

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*[The parties can be redefined, for example if a CRO is a contracting party agreeing under its own name or for the Company. The division of tasks between CRO and Company should be clear and match the separate agreement between Company and CRO.*

*If there is no specific Payee party or 3rd party, i.e. Payee, to the Agreement this Party can also be removed or replaced by Institution dependent on Institution organization]*

**Usability Study Agreement**

This usability study agreement (hereafter “**Agreement**”) is entered into at the last of the days of signature below (“**Effective** **Date**”) between:

1. **[COMPANY]**, located at [address] (“**Company**”), and
2. **[HOSPITAL] HF**, located at [address] (“**Institution**”), and
3. **[PAYEE],** located at [address] (“**PAYEE name**” or “**Payee**”)

**Background**

1. **WHEREAS**, Company is sponsor of the usability study entitled [Usability Study title] (“**Study”**) (as defined below);
2. **WHEREAS**, Company is committed to conduct and manage the Study in Norway.
3. **WHEREAS**, Institution has appropriate facilities and personnel necessary to conduct the Study and will provide the Service of project leader.
4. **WHEREAS**, [Name of Project Leader], will be acting in the role of Project Leader (“**Project Leader**”).
5. **WHEREAS**, Payee is authorized to negotiate and sign the Agreement, and acts exclusively as payee for the financial aspects according to this Agreement, on behalf of the Institution.
6. For the sake of clarity, all obligations applicable to Project Leader according to this Agreement will apply to him/her as an employee of Institution. Accordingly, Project Leader will not be jointly liable for Institution’ responsibilities under this Agreement. Institution shall procure and ensure the performance of the obligations of Project Leader as set out in this Agreement and all applicable laws and regulations.

Agreement

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, the Parties agree as follows:

1. Conduct of the Study

The Parties shall perform the Study according to Protocol entitled [Usability Study title] (“**Protocol**”) in accordance with this Agreement, the Protocol and all applicable laws and regulations. The Institution shall follow all guidelines and instructions reasonably provided by Company.

1. RESPONSIBILTIES AND OBLIGATIONS OF Institution
	1. General responsibilities

The Institution shall be responsible for the conduct of the Study at the Institution. In particular, the following is agreed between the Parties:

Institution shall:

* + - 1. Perform the Study according to all applicable laws and regulations, Institution procedures and written requirements given from Company. The Study shall be carried out in accordance with accepted research practice.
			2. In advance of the commencement date of the Study, obtain internal approval from all necessary parties, at the Institution.
			3. If applicable, in advance of the commencement date of the Study, obtain internal agreements with other Institution departments participating in the provision of the Study.
	1. Institution has full responsibility for personnel and finances for internal staff associated with the Study. Institution is also responsible for filing the required reports for all personal allocations, and bears master-servant liability for internal employees involved with the Study.
	2. Institution is responsible for providing guidance and following up the work of internal employees involved with the Study.
	3. Institution acknowledges that it has been selected to perform the Study hereunder because of its experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, obtaining preferential formulary status for or dispensing any Company’s product.
1. responsibilities AND OBLIGATIONS OF COMPANY
	1. Company shall:
		* 1. If applicable, provide the Project Leader with the required materials and samples as described in the Protocol.
			2. Ensure that the Study is managed according to all applicable law and regulations, and other applicable guidelines provided in writing by Institution.
			3. [Follow Institution guidelines for research that are provided to Company in writing.]
			4. Obtain, if required, approval from appropriate regulatory authorities.
2. REPRESENTATIONS AND WARRANTIES
	1. Institution and if applicable also Project Leader (to the extent that such representations and warranties relate to Project Leader) each represents and warrants to Company:
		* that they will make available adequate time, personnel, facilities and resources to efficiently and expeditiously accomplish its responsibilities under this Agreement, in particular to conduct the Study within the agreed time schedule and in the way set forth in the Protocol;
		* that none of Institution or Study site staff, including Project Leader, it is not subject to any conflicting obligations or legal impediments or has any financial or other interest in the outcome of the Study or has entered into a contract with respect to another study that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by any RA or the grant of rights to Company;
		* that they will promptly notify Company of any potential conflicts of interest that exist or may arise in relation to the Study;
		* that Institution and Study site staff, including Project Leader, are properly registered with appropriate registration bodies and are sufficiently qualified by training and experience for conduct of the Study; and
	2. Institution, to the best of its knowledge, is not currently using, and shall not use the services of any person, including Project Leader, who is debarred, proposed for debarment or otherwise disqualified or suspended from performing a clinical study or otherwise subject to any restrictions or sanctions by any RA and/or ethics committee with respect to the performance of scientific or clinical investigations. Institution will immediately notify Company if Institution becomes aware of any such debarment, proposal for such debarment, disqualification or suspension.
	3. Institution shall comply fully at all times with all applicable anti-bribery and anti-corruption laws, including but not limited to, all applicable anti-bribery and anti-corruption laws of Norway.
3. COMPENSATION
	1. For the services rendered under this Agreement, Company shall pay Institution in accordance with the specification in Appendix 2. Company shall make all payments due under this Agreement to [Institution/Payee], in accordance with Appendix 2. The Parties acknowledge that the amounts to be paid by Company under this Agreement are reasonable compensation, representing the fair market value, for the work performed by Institution, and that neither of Institution or Project Leader have received any other compensation or inducement in connection with this Agreement or their performance of the Services.
	2. In the event that changes to the requested Study require changes to the Study compensation arrangements, an amended financial schedule will be mutually agreed and signed by the Parties and attached as a supplement to Appendix 2 of this Agreement.
	3. Except with respect to those expenses reimbursable under this Agreement, Institution acknowledges and agrees that the payments made by Company as set forth in Appendix 2, as it may be amended from time to time, represent Company’s total obligations under this Agreement. All payments shall be made in accordance with general accepted accounting principles.
4. Intellectual Property
	1. All data, information and documents provided to the Institution or the Project Leader by or on behalf of Company, shall remain the sole property of Company. Institution and the Project Leader will respect all intellectual property rights, including patent, brand, design and copyrights of Company or third party, likewise, Company will respect all intellectual property rights, including patent, brand, design and copyrights of Institution.
	2. Any methods, procedures or other know-how owned or controlled by Institution and used in relation with the Study shall remain the sole property of Institution. Nothing in this Agreement shall constitute a right to Company to use, develop, reverse engineer, manufacture or otherwise exploit Institution’ methods, procedures or other know-how, either by Company itself, any of its affiliates or any third party, either for commercial or for research purposes.
	3. All data, information and results that are collected in writing during the conduct of the Study according to Protocol, including unexpected findings, unforeseen events or results that arise from deviations from the Protocol (“Results”), shall be the sole property of Company. All inventions, discoveries or developments arising from the conduct of the Study, irrespective of inventorship, shall be owned solely by Company. Institution shall assign, and hereby assigns, all of its right, title and interest in any such inventions to Company. Institution agrees to provide necessary assistance, including by execution of any documents, to perfect such assignment to Company of such inventions.
	4. Institution 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 Company under this Agreement.
	5. In the rare event that an Institution -employee is a named inventor on a patent/patent application arising from the Study that is assigned to Company under Section 6.3, and this is the basis of an extraordinary commercial success for Company, the employee(s) may be able to claim a minor remuneration from Institution under the Norwegian law on Employee inventorship (or a succeeding law). If the employee raises any such claim against Institution, Institution shall inform Company immediately and Company and Institution shall jointly decide on how to handle the matter, provided that any compensation to be paid by Institution under such claim following a court decision or a settlement shall be reimbursed by Company.
5. Confidential Information
	1. All information and data, trade secrets, privileged records and other confidential or proprietary information disclosed to or collected or developed by either Party in connection with this Agreement (collectively “Information“) shall be treated as confidential. Each Party (“Receiving Party”) agrees not to disclose to any third parties or to use any Information provided to it by the other Party (“Disclosing Party”) for any purpose other than in connection with the performance of the Study, or, in the case of Company, in connection with the development, regulatory and commercialization activities in connection with Company’s devices or products that are the subject of the Study. Each Party shall ensure that its employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.
	2. The confidentiality obligations set out above shall not apply to:
		* 1. Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by an act or omission of the Receiving Party;
			2. Information that the Receiving Party can demonstrate by written evidence was in its possession prior to its disclosure by disclosing Party or its collection or creation during or in connection with the Services;
			3. Information which the Receiving Party received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favor of either Party on objective grounds had a valid reason to be in good faith regarding such rights.
			4. Information disclosed in permitted publication according to Article 9 of this Agreement.
	3. If disclosure of Information beyond what expressly authorised in this Agreement is required by Norwegian law, that disclosure does not constitute a breach of this Agreement for as long as Institution notifies Company in writing as far as possible in advance of the disclosure so as to allow Company to take legal actions to protect Information, limit disclosure only to Information required to comply with legal obligations, and continue to maintain in confidentiality the Information with respect to all other third parties.
6. Personal Data and Biological Materials
	1. Each Party shall be responsible for its own processing of personal data and shall ensure that any personal data is collected, stored, used, disclosed and transferred in accordance with all applicable supranational and national privacy laws, including terms of approvals from the relevant authorities and ethical committees.
	2. Each Party shall ensure that any collection, handling, use, transportation and retention of biological materials, is carried out in accordance with all applicable laws and requirements. All transferred biological material shall upon completion, or early termination, be returned or destructed, in accordance with the applicable laws and Protocol.
	3. Each Party shall ensure that the security, integrity and quality of the biological materials, are maintained at all times. Each Party shall be responsible for maintaining its own and sufficiently quality assured chain of custody to allow traceability and management of the biological materials.
	4. The Parties will comply with all applicable data protection legislation including without limitation, including the General Data Protection Regulation (EU) 2016/679 (GDPR) (the “Data Protection Legislation”). The Company, as data controller of Study subject and Study Staff personal data collected and sent to Company in accordance with a Study subject’s informed consent and a Study Staff’s consent will comply with Data Protection Legislation and the terms of the respective consent in the processing and use of such data. Institution will remain as data controller of personal data collected and retained in the Institutions patient file in accordance to the Data Protection Legislation and national legislation regarding processing of Personal Health Data.

Acting as Data Controller for the Study Data, Company will be responsible for ensuring that the data are safely delivered by the Institution through the Company’s eCRF or other secure[/approved] solutions in accordance with the Data Protection Legislation, for delivering data, both electronic and physical. Company shall immediately notify Institution in the event that any security measures should fail. In the event that security measures should fail and Company has notified Institution, the Institution shall refrain from delivering data through eCRF or other data capturing system until Company has implemented necessary measures to secure the data transfer. Company shall also ensure that, if study data is made available to anyone outside the EEA, sufficient guarantees should be provided, including organizational and technical measurements, so that further processing of data will be in accordance with the Data Protection Legislation.

1. Publication and Use of Study Results
	1. Company is committed to communicate product, research and development information in an accurate and objective manner. These communication activities must be undertaken in a responsible and ethical manner, taking into account relevant external standards regarding the manner and content of scientific, technical and medical publications. Company fully supports the need for all authors of publications (both Company’s employees and external collaborators) to disclose any potential conflicts of interest including any financial or personal relationships that might be perceived to bias their work.
	2. In the exercise of the rights of academic freedom, Institution and Project Leader (and/or other Study site staff) shall, notwithstanding Article 9 above but subject to this Article 9, have the right to publish the Study results in scientific or other journals, and/or to present the Study results at professional conferences or other meetings. Institution and Project Leader may use the Study results, hereunder data generated at the site, and, in the case the Study is part of a multi-centre study, results from other sites participating in the Study (collectively “Multi-Centre Results”). All external publications or presentations by Institution or Project Leader of such results shall be withheld until the earlier of (i) the date of the first Study results publication by Company, or in case of a multi-centre study the first Multi-Centre Results publication, agreed by the Parties and (ii) the end of the eighteen (18) month period following the completion, or early termination, of the Study at all participating sites. Neither before nor after such date may Institution or Project Leader publish or present any raw data (as distinguished from the results of any analyses of raw data) or make any publication or presentation that is false, misleading, and inconsistent with academic standards or for commercial purposes.
	3. Subject to Article 9.2, at least thirty (30) days prior to submission of any material for publication or fifteen (15) days prior to submission of a presentation, Institution shall provide Company with such material for review. No such publication or presentation may include any of Company’s confidential Information without Company’s prior written approval. If requested in writing by Company, Institution shall withhold, or shall cause Project Leader to withhold, material from submission for publication or presentation for an additional ninety (90) days from the date of Company’s request to allow for the filing of a patent application or the taking of such measures as Company deems appropriate to establish and preserve its proprietary rights in the information in the material being submitted for publication or presentation.
	4. Company and its affiliates shall have the right to independently publish the Study results, subject to Article 9.1 and provided that due acknowledgement is made for the intellectual contribution made by Institution and Project Leader in accordance with standard scientific practice.
	5. Without limitation to any other right of Company hereunder, Institution and Project Leader acknowledge and agree that Company as sponsor will register the Study and, when available, post the Study results in accordance with Company internal policy on one or more publicly-accessible trial registries and websites (including the publicly-funded website ClinicalTrials.gov). Where Institution and Project Leader wish to use a publicly-accessible website on a voluntary basis (e.g. a university/hospital website) the information related to the Protocol must not exceed the information Company has already posted and it should be sufficient to provide a hyperlink to the Study when registered on ClinicalTrials.gov.
2. Use of Name

None of Institution, Project Leader or Company shall mention or otherwise use the name, trademark, trade name or logo of the other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party; provided, however, that Company shall have the right to identify Institution as the site at which the Study was conducted and the responsible Study Site Staff and to use Project Leader’s name in any Company Study recruitment activities.

1. Duty to inform
	1. Institution shall notify Company immediately regarding all circumstances of significance to the Study. Any discovery having a potential for intellectual property rights protection, typically patenting and design protection, shall be reported to Company without undue delay.
2. INSURANCE AND INDEMNITY
	1. Company agrees to indemnify Institution and Project Leader and hold them harmless in respect of and against all claims and proceedings made or brought by or on behalf of Subjects against Institution or Project Leader for personal injury to Subjects, including death, to the extent arising out of or relating to (i) the administration of investigational medicinal product in accordance with this Agreement, the Protocol and any other written instructions of Company, or (ii) the performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study, provided that, in each case:
		* Institution and Project Leader have followed the instructions of Company and complied with the Protocol (and any amendments thereto) and applicable laws and requirements; and
		* Institution and Project Leader have used reasonable medical judgment in the conduct of the Study (including the enrolment of Subjects for which participation in the Study is medically appropriate).
	2. Company’s obligation to indemnify under Article 12.1 will not apply to the extent that such claims or proceedings:
		* arise out of or relate to the gross negligence, wilful misconduct or wrongful act or omission of Institution, Project Leader or any Study site Staff;
		* arise out of or relate to Project Leader’s or Institution’s failure to report promptly to Company any significant or alarming development that has occurred during the Study, including any Subject adverse event or serious adverse event (as both such terms are defined in the Protocol); or
		* arise as a result of Institution’s or Project Leader’s compromise or settlement of any such claim without the written consent of Company.
	3. Company maintains liability insurance in respect of its obligations to third parties and maintains sufficient limits to cover the indemnification obligations in this Agreement.
	4. In accordance with the Norwegian regulation on the State financial management (“Reglement for økonomistyring i staten”, section 20), any Government agency, including all hospitals, shall be self-insurers, which implies that such agencies will not insure its risk through a private insurance company, unless otherwise decided by the Ministry of Finance.
3. Term and Termination
	1. This Agreement commences on the Effective Date and unless this Agreement is earlier terminated under this Article 13, will remain in effect until completion of the obligations of the parties under this Agreement or until the Study is terminated.
	2. Either Party may terminate this Agreement with immediate effect at any time upon written notice if the other Party is:
		* 1. in breach of any obligations under the Agreement 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
			2. ceases to carry out business, goes into liquidation or an administrative receiver or administrator is appointed for the Party or its assets, or enters into a voluntary arrangement with its creditors or suffers any similar insolvency process or in case of any equivalent process occurs in any jurisdiction.
	3. Company may terminate this Agreement upon 30 days written notice to Institution if Project Leader is no longer able (for whatever reason) to act as Project Leader and no replacement mutually acceptable to Company and Institution has been found within reasonable time.
	4. Upon receipt of notice of termination from Company, Institution agrees to terminate the Study as promptly as possible. Institution will use reasonable efforts to wind down the Study, and will provide to Company an accounting of expenses incurred by Institution pursuant to this Agreement. All amounts paid by Company prior to any early termination of this Agreement will be reconciled against the expenses incurred by Institution in performing under this Agreement. If the payments by Company exceed such Institution expenses, Institution will pay to Company any such difference within thirty (30) days after termination of the Study. If the payments by Company are less than such Institution expenses, and such expenditures were contemplated by the Protocol or otherwise authorized by Company, then, subject to the provisions of Article 2, Company will pay to Institution any such difference within thirty (30) days after termination of the Study.
	5. The termination or expiry of this Agreement shall be without prejudice to any rights of the Parties, which shall have accrued prior to or on the final date of termination.
4. INDEPENDENCE

 It is expressly agreed that the Parties will be independent contractors and that the relationship between the Parties will not constitute a partnership, joint venture or agency of any kind. Neither Party will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party.

1. Assignment

Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that Company may assign this Agreement and its rights and obligations hereunder without such consent (i) in connection with the transfer or sale of all or substantially all of the business of Company to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise, or (ii) to any affiliate of Company. The rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement will be void.

1. Notices

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:

**Company:**

[Include details]

**Institution:**

[Include details]

**Payee**:

[Include details]

1. Survival

All clauses that by their nature are meant to survive the termination or expiry of the Agreement, shall survive the termination or expiry of the Agreement.

1. Entire Agreement and Amendment
	1. This Agreement together with the Appendices hereto sets forth all of the agreements and understandings between the parties hereto 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.
	2. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each Party.
2. Inconsistency

In the event of any inconsistency between this Agreement or any other document incorporated therein, including the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects, including Article 8 and 9, the terms of this Agreement shall prevail.

In the event of inconsistency between this Agreement and the confidentiality agreement, the confidentiality agreement shall prevail only regarding confidential information not covered by this Agreement

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. 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 applicable] District Court (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 authorised representatives of Company, Institution and Payee 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..

[*Signature Page Follows*]

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| **COMPANY**[Company]Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[Name] [Title]  | **INSTITUTION**[Institution]Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[Name] [Title]  |
| **PAYEE**[Payee]Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[Name] [Title]  |  |

**READ AND ACKNOWLEDGED;**

Date:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Name]

Project Leader

**Appendix 1:** **[Usability Study Protocol/Project description]**

**Appendix 2: Payment**