**AGREEMENT TEMPLATE**

This is an agreement template for use when the trial are supported from an external/commercial source. This template is developed by NoRCRIN WP12, with support from NorCRIN Legal Group.

See the [Guidance document](https://www.norcrin.no/documents/2022/12/agreement-sponsor-company-guidance.pdf/) for how to adjust and modify the agreement template to the particular clinical trial. If you need legal advice, please consult a legal adviser within your organisation.

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**AGREEMENT FOR SUPPORT FROM EXTERNAL/COMMERCIAL SOURCE**

**by and between**

**SPONSOR**

**(“Sponsor”)**

**and**

**COMPANY**

**(“Company”),**

hereinafter also referred to individually as “Party” and collectively as “Parties”,

regarding

**FULL TITLE OF THE TRIAL AND PROTOCOL NUMBER.**

The Parties have agreed as follows:

1. **Objective and Background**
	1. The objective of this agreement (“**Agreement**”) is to regulate the Parties’ rights and obligations regarding the clinical trial “NAME” under protocol PROTOCOL (“**Trial**”). Trial documentation provided from Sponsor to Company contains a complete description of the proposed trial, including, without limitation, the research objectives, methods, procedures, costs and timelines, available at the time of the proposal. Sponsor shall keep Company updated with any changes or modifications to the Trial documentation. The Trial has received the necessary regulatory and ethical approvals to initiate. The Trial has the following EU CT/EUDAMED/case number: XXX.
	2. The Trial is to be carried out by Sponsor with support by Company. Sponsor is responsible for ensuring it has the appropriate facilities and personnel necessary to conduct the Trial and that participating clinical sites (“**Centres**”) will have the appropriate facilities and personnel necessary to conduct the Trial. NAME, acting as Coordinating Investigator (“**Coordinating Investigator**”), will be coordinating the Trial for Sponsor.
	3. Sponsor and Centres, including Coordinating Investigator and Centres’ Principal Investigators are responsible for providing medical care and to ensure the well-being of the Trial participants (“**Trial Subjects**”) throughout the Trial.
2. **Conduct of the Trial**
	1. Sponsor shall, and shall ensure Centres shall, conduct the Trial in accordance with the applicable laws, regulations, guidelines, and codes of conduct and in accordance with all applicable regulatory approvals, and terms and conditions of this Agreement.
	2. Sponsor has undertaken, and shall ensure each Centre undertakes, the responsibility for ensuring the Trial is conducted in accordance with the current protocol and any amendments to the protocol, only after all necessary legal and regulatory approvals have been granted and strictly in accordance with the terms of any such approvals.
3.
4. **Main responsibilities of the Parties**
	1. **Sponsor Responsibilities**
	2. Sponsor shall be responsible for:
* the operational management of the Trial and its participating clinical sites;
* ensuring that regulatory approvals of the Trial for all sites are obtained; ensuring sufficient and high quality monitoring, central data management and analysis of the Trial data;
* preparing regular reports, including safety reports, with information to the Centres and the relevant authorities, according to applicable regulatory requirements;
* ensuring that the Trial is properly registered in Clinical Trial Information System – CTIS/EUDAMED/relevant registers,
* ensuring an adequate trial insurance as required by applicable regulatory requirements to cover any claims of Trial Subjects; notifying Centres about Trial closing or early discontinuation;
* undertake any reasonable effort to publish the results according to section 7 of this Agreement;
* report to Company all individual Serious Adverse Reactions related to Company’s IMP within the same timeline as if they were reportable to regulatory authorities; and
* report to Company any pregnancy in subjects receiving Company’s IMP.
	1. Sponsor shall provide Company with the Trial result summary intended for publication in the applicable clinical trial database, the final Trial report and information for public dissemination in accordance with section 7 of this Agreement.
	2. Sponsor may use Company Support (defined in section 3.8 etc.) only for the purposes of Trial.
	3. Sponsor shall, and shall ensure Centres shall, handle, store, and use the Investigational Medicinal Product as defined in the Protocol (“**IMP**”) in accordance with the protocol and all applicable laws and regulations.
	4. Sponsor shall ensure all unused, partially used, and expired IMP or other trial drug or placebos, shall be destroyed in accordance with local procedures by Centres. Centres shall only destroy the IMP upon approval by Sponsor.
	5. Sponsor shall, and shall ensure Centres shall, handle, store, and use the Medical Device as defined in the Protocol (“**MD**”) in accordance with the protocol and all applicable laws and regulations.
	6. **Company Responsibilities**
	7. Company shall support the trial with the following support(**“Company Support”**):
	8. Company shall provide funding to the Sponsor to support the Trial, in accordance with the budget included in Appendix A.
	9. Company shall provide Sponsor with the required quantities of the IMP for the sole purpose of conducting the Trial and all current and relevant information regarding the IMP. IMP shall remain the exclusive property of Company until administered or dispensed to Trial Subjects during the Trial.
	10. Company shall provide Sponsor with the required quantities of MD for the sole purpose of conducting the Trial and all current and relevant information regarding the MD. MD shall remain the exclusive property of Company until administered or dispensed to Trial Subjects during the Trial.
	11. **General**
	12. The Parties agree that the Trial represents bona fide research and that Company Support provided by Company under no circumstances is meant to put an obligation or expectation on Sponsor to purchase, order, prescribe, or recommend any Company product or otherwise engage in business with Company. The support provided by Company is not conditioned on any pre-existing or future business relationships.
1. **Liability, Insurance, and Indemnity**
	1. Sponsor shall take out an insurance as required by applicable regulatory requirements. The insurance shall cover compensation to Trial Subjects suffering injury or death or loss caused by the administration of the Trial Drug or any clinical intervention or procedure carried out in accordance with the protocol and legal requirements laid down by regulations where the Trial is conducted.
	2. A Party that wishes to invoke a contractual breach under this clause shall, without undue delay after the Party became aware of or should have become aware of the contractual breach in question, inform the other Party and give a written justification.
	3. Each Party shall indemnify and hold harmless the other Party, its agents, and employees from any and all duly evidenced liabilities, claims, actions, or suits to the extent caused by its negligence or wrongful acts or omissions; or the negligence or wrongful acts or omissions of its agents or employees pertaining to the activities to be carried out pursuant to the obligations under this Agreement. A Party shall promptly notify the other in writing of any such complaint, claim or injury relating to any loss subject to this indemnification.
	4. Under no circumstances shall any of the Parties be liable for any indirect, special, incidental, punitive, or consequential damages, including, but not limited to, loss of profits.

1. **Trial Data and Intellectual Property**
	1. For the purpose of the Agreement, the right of ownership to any software, inventions, patent applications, patents, know-how, data, results, intellectual property controlled or owned by either Party prior to the date of the Agreement, or intellectual property generated by either Parties independent of the Trial and controlled or owned by that Party (“**Background**”), shall belong to the Party owning such Background prior the conclusion of the Agreement.
	2. (1) Any results, generated in direct connection to the Trial, hereunder data, theories, methods, and knowhow, regardless of form, and other results capable of protection pursuant to patent law, trademark law, design law, or any other legal acts (“**Results**”) shall belong to the Sponsor and/or participating Centres.
	3. (2) Any results, generated in direct connection to the Trial, hereunder data, theories, methods, and knowhow, regardless of form, and other results capable of protection pursuant to patent law, trademark law, design law, or any other legal acts (“**Results**”) shall belong to the Sponsor. Notwithstanding, all Trial personal data shall be the property of Sponsor and/or participating Centres, and will under no circumstances be licensable or otherwise transferable under this Agreement.
	4. (2) Sponsor hereby grants to Company an option to, under fair and reasonable conditions, have the rights to Results transferred to it, and shall have a right of first refusal. Company agrees to consider and exercise its right of first refusal within a reasonable timeframe and always within fifteen (15) days after receiving a notice of a third party offer.
	5. (3) Any results, generated in direct connection to the Trial, hereunder theories, methods, and knowhow, regardless of form, and other results capable of protection pursuant to patent law, trademark law, design law, or any other legal acts (“**Results**”) shall belong to the Company. Company shall be responsible for taking the necessary steps to protect their rights in the Results and shall be responsible for any fees or other costs related to the transfer and ownership of Results. Notwithstanding, all Trial personal data shall remain the property of Sponsor and/or participating Centres, and will under no circumstances be licensable or otherwise transferable under this Agreement.
	6. Sponsor shall ensure that the Coordinating Investigator and Principal Investigators employed by Centres that are to perform services in connection with the Trial, acknowledge and are obliged to execute any documentation reasonably required to give effect to any transfer of rights to Results.
	7. (2) (3) Nothing herein, however, shall prevent Sponsor and Centres from using any information generated hereunder, including Results for internal, non-commercial research and educational purposes. Company hereby grants to Sponsor a worldwide, irrevocable, indefinite, transferrable to Trial’s Centres, and royalty free right to use Results for internal, non-commercial research and educational purposes.
	8. Company may request access to Trial personal data if a regulatory agency requests such information, and Sponsor shall provide to regulatory agency said information, when in compliance with applicable law and/or regulatory/ethical waiver.
2.
3. **Confidentiality**
	1. Each Party is obliged to keep confidential the content of this Agreement, the information the Party receives from the other Party for the performance of the Trial and the information the Party receives about the other Party and its business in connection with the Agreement and the implementation of the Agreement ("**Confidential Information**"). One Party shall not disclose Confidential Information without the consent of the other Party, unless:
		1. as provided for in this Agreement;
		2. such disclosure is required by law; or
		3. the relevant Confidential Information is already generally known.
	2. Either Party shall promptly notify the other Party if it receives a legally binding request to disclose Confidential Information, and shall take reasonable steps to minimise the extent of any such required disclosure.
	3. Each Party shall use at least the same degree of care and security to maintain the Confidential Information confidential as it uses to maintain its own Confidential Information confidential, but always at least a reasonable degree of care. The Parties shall implement technical, physical and organisational safeguards to ensure an adequate level of security appropriate to the risks.
	4. Access to Confidential Information shall be limited to persons requiring access on a need to know basis. The Parties shall revoke access authorisations for employees or other individuals who no longer need said authorisation.
	5. Each Party shall make sure that the Confidential Information is protected from unauthorised access. Each Party shall promptly notify the other Party about any deviation concerning access, both accidental and unauthorised, to the Confidential Information and shall take reasonable steps to regain access control and confidentiality.
4. **Dissemination of Results**
	1. Sponsor shall ensure that the Trial results are publicly disseminated and that such disclosure is made in an objective and correct manner in line with the Helsinki Declaration. The dissemination shall include both desired and unwanted results.
	2. Publications shall refer to the contributors according to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals (“**Vancouver Recommendations**”). Co-authorship shall be based on the criteria of the Vancouver Recommendations. Contributions that do not qualify for co-authorship shall be awarded acknowledgement in accordance with the Vancouver Recommendations.
	3. (1) Material for public dissemination will be submitted to Sponsor for review at least thirty (30) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor is responsible to provide material to other research sites or third parties with possible intellectual property rights and request their feedback within the agreed time limits. If neither Sponsor nor any other research site or third party request additional time to take steps to protect their Results within this thirty (30) day period, Centres are free to proceed with the intended publication or presentation without further delay. An entity requesting postponing the public dissemination of material to protect Results in connection to the Trial shall be given reasonable time to take the necessary legal steps to protect their Results, however never more than 90 days counting as of having requested deferral of the public dissemination.
	4. (2) Material for public dissemination will be submitted to Sponsor for review at least thirty (30) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor shall provide a copy to Company and permit at least ten (10) days for Company’s review and comments. Company is responsible for providing Sponsor with its feedback within ten (10) days if Company has any feedback or requests delay to seek protection of any Results. An entity requesting postponing the public dissemination of material to protect Results in connection to the Trial shall be given reasonable time to take the necessary legal steps to protect their Results, however never more than 90 days counting as of having requested deferral of the public dissemination.
5. **Inspection**
	1. Sponsor shall ensure all Centres and Sponsor shall allow any national regulatory authorities to inspect the Trial on site.
6. **Commencement, Term, and Termination**
	1. This Agreement takes effect on the date the Agreement has been signed by both Parties and shall continue to regulate the Parties’ rights and obligations regarding the Trial until the completion of all Trial activities, or until otherwise terminated as provided for in this Agreement.
	2. This Agreement may be terminated with immediate effect by Sponsor by written notice to Company in the case of early termination or pause of the Trial; any technical, administrative cause, or methodological impossibility to pursue the Trial; or due to a contractual breach caused by Company and its agents.
	3. In the event of a material breach by one Party, due to errors or misconduct, the other Party may terminate the Agreement with immediate effect if the Party causing the contractual breach has not remedied the breach in a satisfying manner within thirty (30) days after receiving a notice identifying the breach and a reasonable remedy.
	4. Compensation for tasks carried out up to termination remain payable.
	5. For the avoidance of doubt, force majeure means any unforeseeable and exceptional event affecting performance of the Agreement, which is outside the control of the Parties, and which cannot be avoided in spite of the efforts which the Parties may reasonably make (“**Force Majeure**”).
	6. No Party shall be considered to be in breach of this Agreement if such breach is caused by Force Majeure. Each Party shall notify the other Party of any Force Majeure as soon as possible. If impossibility or delay in fulfilment due to a case of force majeure continues for longer than 90 days, the latter Party may automatically terminate the Agreement at any time by written notification sent to the other Party.
	7. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination.
	8. Upon expiration or termination of this Agreement, the obligations that by their nature are intended to survive expiration or termination of the Agreement.
7. **General Provisions**
	1. No terms, conditions, understanding, or agreement purporting to modify or vary the terms of this Agreement shall be binding unless hereafter made in writing and signed by all Parties.
	2. If any provision of this Agreement is deemed to be, or become, ineffective or is found null or void, the remaining provisions shall remain in full force and effect. Such invalid, null, void, or ineffective provision shall be replaced by a provision which is valid and which best reflects the purpose of the original ineffective provision. The same shall apply to any omissions herein.
	3. No failure or delay of either Party to give notice of any breach or to exercise any right or remedy under this Agreement shall be construed as a waiver of any right or obligation thereof, nor shall it preclude the exercise of any other rights under this Agreement.
	4. A Party may not assign, or purport to assign, or transfer a right or obligation under this Agreement without having first obtained the other Party’s prior written consent, which may not be unreasonably withheld or delayed.
	5. The Agreement is governed by the laws of Norway, excluding Norwegian conflict of laws principles providing for the application of laws of any other jurisdiction.
	6. In case of any disputes arising out of or in connection with this Agreement, the Parties shall first seek an amicable resolution. If the Parties do not find an amicable solution, claims can be raised before the agreed venue, INSERT District Court, without restricting any right of appeal.
	7. Each Party warrant and represent to the other that it has the full and all right and authority to enter into this Agreement and is unaware of any impediment that would inhibit its ability to perform its obligations hereunder.
	8. (1) This Agreement is made in two original copies. (2) This agreement is signed using electronic signatures.
8. **Appendices**
	1. The appendices to this Agreement, which form an integral part of this Agreement, are the following:

Financial compensation

Protocol

* 1. In case of conflict between the terms of this Agreement and the terms of its Appendices the terms of this Agreement shall prevail.

# Signatures

For and on behalf of the Company:

NAME:

TITLE:

DATE: SIGNATURE:

NAME:

TITLE:

DATE: SIGNATURE:

For and on behalf of the Sponsor:

NAME:

TITLE:

DATE: SIGNATURE:

NAME:

TITLE:

DATE: SIGNATURE:

READ and ACKNOWLEDGED by Coordinating Investigator:

NAME:

TITLE:

DATE: SIGNATURE: