**COLLABORATIVE RESEARCH AGREEMENT**

**MATERIAL and DATA SHARING AGREEMENT**

This Collaborative Research Agreement (“**Agreement**”), effective as of the date of the last signature (“**Effective Date**”) is made between:

(hereinafter referred as **“Principal/Co-Investigator”**), as \_\_\_\_\_\_\_\_\_\_\_\_\_\_of Department of Medicine, College *of Medicine,* **King Saud University and University Medical City (KSU/KSUMC),** at P.O. Box 7805 Riyadh 11472, Saudi Arabia. -and-

(hereinafter referred as **Co-investigator”**), as \_\_\_\_\_\_\_\_\_\_, at (hereinafter “**Institution**”).

Institution and Principal Investigator hereinafter referred to collectively as the **‘second party’,** and/or **‘recipient’,** *as* collaborative site complete address.

Each party is hereinafter referred to individually as a **“Party”** and collectively as **“Parties”**

Any ***Material (***patients/subject’s sample***)*** and/or ***Data*** provided by ‘either party’ under this Agreement is regulated in accordance to the applicable laws of Kingdom of Saudi Arabia and following the approval of the local ethics committee.

**WHEREAS**, Principal Investigator wishes to conduct the following clinical trial/research study entitled “ “in KSUMC and desires to serve as principal investigator for the Study, pursuant to applicable laws;

**WHEREAS**, the provisions of the applicable laws in Kingdom of Saudi Arabia, allows the

Investigators to conduct research in compliance with ethical principles;

**WHEREAS**, The Principal Investigator has the expertise and the Institution has the necessary resources relating to clinical trial/research design, conduct, evaluation and analysis;

**WHEREAS**, recipient had determined that the Study is of interest to the recipient and recipient desires to provide, not limited to, (technical support, analysis, and fund in connection) with the Study;

**THEREFORE**, in consideration of the premises and of the mutual covenants, conditions and agreements contained herein, the parties agree as follows:

# SITE SHARING CONDITIONS

The Material and/or Data will be made available to the first Party as part of conducting the Research Project, approved by the local ethics committee and, if applicable, relevant regulatory authority, set forth under the following conditions:

▪ The first Party will receive the shared patient Material and/or Data on the terms of this Agreement and solely for the purpose of conducting the Research Project as described in attached approved protocol.

When patients’ material and data is to be transferred from the ‘either parties, to another country, an agreement stating the standard contractual clauses for transfer will also be signed, in accordance with **The Personal Material and Data Protection Law (PDPL) is the main material and Data protection law in KSA** (Resolution No. 98; Royal Decree M/19 of 9/2/1443H (16 September 2021), under the authority of Saudi Material and Data and Artificial Intelligence Authority (**SDAIA**) and National Material and Data Management Office (**NDMO**).

**The National Committee of Bio-Ethics (NCBE)** must be notified, in case the material is sent outside the Kingdom, to the third party, as part of the approved research study procedures. NCBE form (sending bio-specimen abroad\_2.0) should be filled mandatory along with the other contractual/collaborative forms/documents.

The Material and/or Data will be made available for the receiving Party without any direct personal identification to the human subjects such Material and/or Data have been derived from. The receiving Party must under no circumstances attempt to re-identify material and Data subject’s by adding study code.

The Material and/or the Material and Data derived from the Material, OR any other Clinical Material and Data, may only be used under the first Party’s direct supervision and under suitable containment and protected conditions, and in compliance with applicable laws, regulations and necessary approvals.

Each Party is responsible for all handling and storage of said Material and/or Data in compliance with all laws, rules and regulations applicable to the handling and use of the materials/sample(s).

The receiving Party will not transfer the Material or/and Data to any other body, or permit its use within its own Institution other than within the collaborating research group, without (in each case) prior written consent from the first Party and required approvals.

The Material and/or Data may not be used in activities subject to the provision of any rights to a commercial third party without prior written consent from the providing Party and required ethical, legal and regulatory approvals.

Except to the extent prohibited by law, the first Party assume all liability for damages which may arise from its own use, storage or disposal of the Material and/or Data. The Parties will not be liable to the other Party for any loss, claim or demand due to, or arising from the use of the Material and/or Data.

The liability of either Party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

Upon completion of the Research Project or termination of this Agreement (whichever comes first), the receiving Party will return or destroy all Material and/or Data as instructed by the providing Party.

# PROPOSED AMENDMENTS

This Agreement constitutes the entire agreement between the Parties in respect of the Approved Research Project. Any amendments and changes to this Agreement shall be applicable only, approved by the local ethics committee, if proposed in writing and signed by an authorized signatory of each Party.

# STUDY CONDUCT

Protocol. The protocol for the study is described in details in the submitted and attached research proposal titled: **\_\_\_\_\_\_\_\_\_\_\_** The protocol will guide the performance of the study. The study involves the enrollment of evaluable subjects who meet all of the protocol eligibility requirements ("**Subjects**").

Protocol Deviations. If generally accepted standards of ICH Harmonized Tripartite Guidelines for Good Clinical Practice ("**GCP**") relating to the safety of subjects require a deviation from the protocol, these standards shall be followed. PRINCIPAL INVESTIGATOR may also from time to time make changes to the protocol. Any such changes may not be implemented before approval by the applicable IRB/IEC and before review by the Site. Site may terminate this agreement if the study is no longer of sufficient scientific interest to the Site as a result of such a change.

# CONFIDENTIALITY

The confidentiality of material and data pertaining to individuals will be protected as follows:

1. The material and data recipient will not release the names of individuals, or information that could be linked to an individual, nor will the recipient present the results of material and data analysis in any manner that would reveal the identity of individuals.
2. The material and data recipient will not release individual addresses, nor will the recipient present the results of material and data analysis in any manner that would reveal individual addresses.
3. Both parties shall comply with all applicable laws and regulations governing the confidentiality of the information that is the subject of this Agreement.
4. All parties shall implement appropriate technical and organizational measures to protect the Personal Material and Data and Confidential Information as required by ICH-GCP and Material and Data Protection and Privacy Laws
5. These confidentiality obligations will continue until five (5) years after completion of the Study, but will not apply to information to the extent that it: (i) is or becomes publicly available through no fault of Site; (ii) is disclosed to Site by a third party not subject to any obligation of confidentiality; (iii) must be disclosed to IRBs; (iv) is permitted to be disclosed under an ICF; or, (v) is required to be disclosed by Applicable Law, including to report public health/safety information.

# PUBLICATIONS

1. The Institution and the Principal Investigator shall be entitled to publish the results of, or make presentations related to, the Study. If this Study is part of a multi-center clinical trial, Institution and Investigator agree not to independently publish the results of the Study until first occurrence of one of the following: (i) multi-center primary Publication is published; (ii) no multi-center primary publication is submitted within two years after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-center primary Publication.
2. ***Ownership****.* The Institution may maintain one archival copy of all Proprietary Information for the purpose of demonstrating its compliance with its obligations hereunder. Each Party will disclose to the other Party a summary of all Material and Data generated under this Agreement. Both Parties will have free access to and use of any Material and Data generated under this Agreement. Both Parties will use reasonable efforts to keep Material and Data confidential until published or until corresponding patent applications are filed
3. ***Authorship****.* Authorship for all publications will be in accordance with the criteria defined by the International Committee of Medical Journal Editors (ICMJE). These state that: "Each author should have participated sufficiently in the work to take public responsibility for the content." For the primary publication, order of authorship shall be determined based on contribution to the Study in accordance with ICMJE criteria. Site shall be included in the affiliations of the Investigator for publications out of the material and data generated.

**USE AND RETURN OF MATERIALS /EQUIPMENT (if applicable only otherwise, please delete)**

Sponsor may provide certain equipment to the Site for use by the Investigator for purposes of the conduct of the Study ("Material/Equipment"). The Site may use the Material/Equipment only for purposes of the Study, in accordance with any manuals or instructions while in possession of the Site. Sponsor is responsible for all out-of-pocket expenses associated with the delivery, installation and return of Material/Equipment and the maintenance.

Sponsor shall arrange to collect them from the Site or arrange for its disposal at its own cost as soon as reasonably practicable thereafter.

# TERM AND TERMINATION

Right to Terminate. Principle Investigator shall have the right, at any time, to immediately suspend or terminate this Agreement, with or without cause and in whole or in part, upon ten (10) days prior written notice to Site specifying the date and extent of termination.

Site’s Right to Terminate. Site shall have the right to terminate this Agreement: (i) upon the occurrence of an event qualifying as a termination event as described in the Protocol; (ii) the institution Material and Data Safety and Monitoring Board reports (DSMB) or (iii) upon a written notice by the Principal Investigator that the Study should cease in the interests of the Subjects.

Any party may Terminate. the Clinical Trial/research study at any time immediately upon written notice to the other parties if: (i) necessary to protect the safety, rights or welfare of subjects enrolled in the Clinical Trial; (ii) as a result of an order of any government authority; (iii) the approval from the Institutional Review Board is withdrawn; (iv) any other Party commits a material breach of any of its obligations under the Agreement and fails to remedy such breach (where possible) within thirty (30) days of written notice from a non-defaulting Party.

Obligations Upon Termination. Upon termination, Site shall: (i) preserve any material and data relating to the Study; (ii) turn over such material and data; and (iii) furnish recipient an acceptable investigator's report for the Study.

# RECORD RETENTION

Institution and Investigator will retain in a safe and secure location at least one (1) copy of all printed and electronic material and data and reports resulting from their conduct of the Study for the longer of (a) five (5) years following completion, abandonment or termination of the Study or (b) the period required by applicable law or regulation.

# COUNTERPARTS

This agreement may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

# FORCE MAJEURE

Neither Party will be responsible or liable to the other Party for non-performance or delay in performance of any terms or conditions of this Agreement due to acts or occurrences beyond the control of the nonperforming or delayed Party, including, but not limited to, acts of God, acts of government, terrorism, wars, riots, strikes or other labor disputes, shortages of labor or materials, fires, and floods, provided the nonperforming or delayed Party provides to the other Party written notice of the existence of and the reason for such nonperformance or delay.

# GOVERNING LAW AND JURISDICTION

This Agreement and any dispute or claim arising out of or in connection with it or its subject matter shall be governed by and construed in accordance with the laws of Kingdom of Saudi Arabia. The Parties irrevocably agree that the courts of Kingdom of Saudi Arabia shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter.

# ACKNOWLEDGED AND AGREED BY THE RECIPIENT

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:**

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# ACKNOWLEDGED AND AGREED BY THE IT DIRECTOR

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# ACKNOWLEDGED AND AGREED BY THE CHIEF MEDICAL OFFICER

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_