

MEMORANDUM OF UNDERSTANDING

BETWEEN



MAJOR SD SINGH UNIVERSITY
Kanpur Road, Fatehgarh, Farrukhabad, Uttar Pradesh.
(Hereinafter referred to as "MSDSU")



AND

KREOLE BIOTECH INC.
Raheja Platinum, Sag Baug Road,
Marol, Andheri East,
Mumbai – 400059, Maharashtra
(Hereinafter referred to as "Kreole Biotech")

FOR

"ARTHRITIS FREE INDIA INITIATIVE"

Academic, Clinical, Research, Human Clinical Trials & Community Health Collaboration

This Memorandum of Understanding is entered into between **Major SD Singh University, Kanpur Road, Fatehgarh–Farrukhabad, Uttar Pradesh** and **Kreole Biotech Inc., Mumbai, Maharashtra**, with the objective of establishing academic, clinical, research, training and community-oriented collaboration in the areas of **arthritis, musculoskeletal disorders, bone and joint health, rehabilitation, preventive healthcare, integrative medicine and healthy ageing**.

Both parties recognize the increasing burden of osteoarthritis, rheumatoid arthritis, osteoporosis, age-related joint disorders, musculoskeletal pain and disability. Accordingly, they intend to collaborate under the **"Arthritis Free India Initiative"** for awareness, prevention, early detection, appropriate referral, scientific research and evidence-based management.

1. OBJECTIVES OF THE MoU

The primary objectives of this MoU shall be:

1. To create awareness regarding arthritis, joint disorders, osteoporosis, musculoskeletal diseases and healthy ageing.
2. To promote early screening and timely identification of individuals at risk of arthritis and related disorders.
3. To conduct joint health awareness programmes, screening camps and community outreach activities.
4. To promote an integrated and multidisciplinary approach involving Ayurveda, modern healthcare, physiotherapy, nutrition, lifestyle modification and rehabilitation, wherever appropriate.
5. To organize academic and scientific activities for students, interns, faculty members, healthcare professionals and the general public.
6. To facilitate collaborative scientific research related to arthritis, bone and joint disorders and musculoskeletal health.
7. To promote and undertake ethical human-participant research and human clinical trials, subject to all applicable regulatory and ethical approvals.

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8. To encourage preventive measures including physical activity, weight management, balanced nutrition and appropriate exercise.
9. To develop scientific and educational material for improving public understanding of arthritis and joint health.

2. AREAS OF COLLABORATION

A. Arthritis Awareness & Community Outreach

Both parties may jointly organize:

- Arthritis awareness campaigns
- Bone and joint health camps
- Osteoarthritis screening programmes
- Community health awareness programmes
- Rural and urban outreach activities
- Awareness programmes for elderly populations
- World Arthritis Day and other relevant health observances
- Patient education sessions
- Lifestyle modification programmes
- Nutrition and exercise awareness activities
- Musculoskeletal disability prevention programmes

B. Clinical Screening & Early Detection

Subject to institutional and regulatory requirements, activities may include:

- Preliminary arthritis and joint-health assessment
- Screening for musculoskeletal problems
- Assessment of mobility and functional limitations
- Identification of individuals requiring specialist consultation
- Appropriate referral to relevant departments
- Patient counselling and follow-up awareness
- Screening for osteoporosis and fracture risk, wherever appropriate

Clinical diagnosis and treatment shall remain under the responsibility of appropriately qualified and registered healthcare professionals.

3. COLLABORATION WITH THE INSTITUTE OF AYURVEDA

Special emphasis may be given to collaboration with the **Institute of Ayurveda, Major SD Singh University**, including academic, clinical and research activities related to:

- Kayachikitsa
- Panchakarma
- Shalya Tantra
- Shalakya Tantra, wherever relevant
- Swasthavritta & Yoga
- Dravyaguna
- Rasashastra & Bhaishajya Kalpana
- Roga Nidana
- Rehabilitation

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- Lifestyle medicine
- Integrative management of musculoskeletal disorders

Collaborative activities may explore scientifically appropriate integrative approaches to arthritis, pain, rehabilitation and joint health while adhering to applicable professional and regulatory guidelines.

4. ACADEMIC ACTIVITIES

Both parties may collaborate in conducting:

- Continuing Medical Education (CME) programmes
- Faculty Development Programmes
- Workshops
- Seminars
- Conferences
- Guest lectures
- Webinars
- Clinical case discussions
- Student and intern orientation programmes
- Skill-development programmes
- Research methodology training
- Good Clinical Practice orientation
- Clinical trial awareness programmes

Special academic sessions may focus on:

- Osteoarthritis
- Rheumatoid arthritis
- Osteoporosis
- Joint and cartilage health
- Chronic musculoskeletal pain
- Bone healing
- Geriatric musculoskeletal health
- Nutrition in bone and joint disorders
- Rehabilitation and physiotherapy
- Preventive and lifestyle medicine
- Ayurveda and integrative approaches
- Clinical research methodology

5. PHYSIOTHERAPY, EXERCISE & REHABILITATION

Both parties may promote structured programmes related to:

- Joint mobility
- Muscle strengthening
- Physiotherapy
- Rehabilitation
- Appropriate walking and physical activity
- Posture correction
- Fall prevention

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- Exercise programmes for elderly patients
- Lifestyle modification
- Functional rehabilitation
- Patient-specific exercise education

Qualified professionals shall supervise clinical or therapeutic activities wherever required.

6. RESEARCH & SCIENTIFIC COLLABORATION

Both organizations may explore opportunities for:

- Joint observational studies
- Clinical research
- Epidemiological studies
- Community-based arthritis surveys
- Quality-of-life studies
- Bone and joint health research
- Lifestyle and nutritional research
- Integrative medicine research
- Ayurveda-based research
- Rehabilitation research
- Research publications
- Scientific presentations
- Development of research protocols
- Multicentric research
- Investigator-initiated studies
- Sponsor-supported research

The collaboration may also include **human clinical trials and interventional studies**, subject to all applicable ethical, scientific and regulatory approvals.

7. HUMAN CLINICAL TRIALS & HUMAN PARTICIPANT RESEARCH

Both parties may collaborate in conducting **human clinical trials, interventional studies, observational studies, post-marketing studies, comparative clinical studies and other human-participant research** related to arthritis, musculoskeletal disorders, bone and joint health, Ayurveda interventions, pharmaceutical or nutraceutical products, rehabilitation and integrative healthcare.

Such research may include:

- Evaluation of safety, efficacy and tolerability of investigational products or interventions
- Clinical evaluation of Ayurvedic formulations and therapies
- Clinical studies involving pharmaceutical, nutraceutical or herbal products
- Comparative studies of conventional, Ayurveda and integrative treatment approaches
- Post-marketing surveillance studies
- Real-world evidence studies
- Patient-reported outcome studies
- Quality-of-life studies
- Rehabilitation and physiotherapy intervention trials
- Lifestyle intervention studies
- Investigator-initiated clinical trials

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- Sponsor-supported clinical trials
- Multicentric clinical trials, wherever mutually agreed and permissible
- Bioavailability or other clinical studies, wherever relevant and legally permissible

Regulatory and Ethical Requirements

No human clinical trial or interventional research shall commence solely on the basis of this MoU.

Every such study shall require a separate duly approved research protocol and shall be undertaken only after obtaining all necessary approvals, including, wherever applicable:

- Institutional Ethics Committee approval
- Clinical Trials Registry-India registration
- Written informed consent from every participant
- Approval or permission from competent regulatory authorities
- Compliance with applicable ICMR ethical guidelines
- Compliance with applicable CDSCO requirements
- Compliance with the New Drugs and Clinical Trials Rules, 2019, wherever applicable
- Compliance with Good Clinical Practice requirements
- Appropriate adverse-event reporting
- Serious adverse event management
- Trial-related medical management and compensation, wherever applicable
- Appropriate insurance or indemnity arrangements, wherever required
- Protection of participant privacy and confidentiality
- Maintenance of essential trial documents and records
- Appropriate trial monitoring and quality assurance

The rights, safety, dignity and well-being of human participants shall remain the **highest priority** in all collaborative clinical research.

8. SEPARATE CLINICAL TRIAL / RESEARCH AGREEMENT

For every human clinical trial or major research project, a **separate Clinical Trial Agreement / Clinical Research Agreement / Project Agreement** shall be executed between the concerned parties.

Such agreement may define:

- Study protocol
- Principal Investigator and research team
- Sponsor responsibilities
- Investigator responsibilities
- Financial arrangements
- Investigational product supply
- Storage and accountability of investigational products
- Participant recruitment
- Insurance
- Compensation
- Monitoring
- Data ownership
- Data access
- Publication rights

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- Intellectual Property Rights
- Adverse-event reporting
- Regulatory responsibilities
- Audit and inspection requirements
- Confidentiality
- Study termination provisions

9. STUDENT & FACULTY ENGAGEMENT

The collaboration may provide opportunities for:

- Student participation in health awareness programmes
- Internship-related observational exposure, where permissible
- Faculty interaction
- Research mentorship
- Academic projects
- Scientific poster and paper presentations
- Community health activities
- Training in patient education
- Research methodology training
- Exposure to clinical research processes
- Clinical data-management orientation, where permissible

Students shall not independently undertake activities requiring professional registration or regulatory authorization.

10. "KREOLE 6 VALUES" AWARENESS CONCEPT

Under the *Arthritis Free India Initiative*, educational programmes may incorporate the following health-promotion principles:

K – Knowledgeable:

Promoting scientifically correct information regarding arthritis and musculoskeletal disorders.

R – Resilient:

Encouraging appropriate and regular physical activity.

E – Energetic:

Promoting healthy nutrition and an active lifestyle.

O – Optimistic:

Encouraging a positive approach towards long-term disease management.

L – Loyal:

Encouraging adherence to professional medical advice, prescribed treatment and rehabilitation.

E – Enthusiastic:

Promoting active participation in family, social and daily activities within medically appropriate limits.

All educational messaging shall be subject to appropriate scientific and institutional review.

11. PUBLIC HEALTH & PATIENT EDUCATION MATERIAL

Both parties may jointly develop or support:

- Patient information leaflets
- Posters

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- Educational booklets
- Digital awareness material
- Videos
- Social-media awareness campaigns
- Arthritis prevention guidelines
- Lifestyle and exercise information material
- Educational content for students and health professionals

Use of the name, logo or emblem of either party shall require prior written approval.

12. PRODUCT PROMOTION & CLINICAL INDEPENDENCE

This MoU is intended primarily for **academic, research, clinical-awareness and community-health collaboration**.

Nothing contained in this MoU shall:

- compel any doctor to prescribe a particular product;
- create an obligation upon the University or its hospital to purchase any product;
- be construed as institutional endorsement of any specific pharmaceutical, nutraceutical or herbal product;
- interfere with the independent clinical judgment of healthcare professionals;
- permit direct promotional claims without scientific and regulatory compliance.

Any product-related scientific discussion, evaluation, sampling, research or clinical trial shall comply with applicable laws, ethical standards and institutional policies.

13. FINANCIAL ARRANGEMENTS

This MoU does not, by itself, create any automatic financial liability upon either party.

Financial arrangements for any specific programme, research project, clinical trial, camp, workshop or other activity shall be decided separately through mutual written consent prior to commencement.

For sponsored clinical trials, financial terms shall be governed by a separate agreement.

14. CONFIDENTIALITY & DATA PROTECTION

Both parties shall maintain confidentiality of proprietary, research, patient-related and institutional information exchanged during the collaboration.

Patient or participant information shall not be disclosed or used for commercial or promotional purposes without proper authorization and compliance with applicable law.

All human research data shall be collected, stored, processed and used only for approved scientific purposes.

15. INTELLECTUAL PROPERTY RIGHTS

Intellectual Property generated through jointly undertaken projects shall be governed through mutually agreed terms on a project-to-project basis.

Neither party shall use the other party's name, logo, trademark, research data or intellectual property without prior written permission.

16. PUBLICATION OF RESEARCH

Scientific publications resulting from collaborative research shall acknowledge the contribution of both parties in accordance with accepted authorship and research-ethics principles.

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Publication shall be subject to:

- Institutional policy
- Ethical requirements
- Confidentiality obligations
- Intellectual Property considerations
- Terms of the specific research agreement

No party shall unreasonably suppress legitimate scientific findings.

17. ETHICS, SAFETY & SCIENTIFIC INTEGRITY

Both parties agree to maintain:

- Scientific integrity
- Ethical research practices
- Participant safety
- Accurate data recording
- Transparent reporting
- Appropriate conflict-of-interest disclosure
- Compliance with applicable laws and guidelines

Fabrication, falsification, manipulation or unethical use of clinical data shall not be permitted.

18. COORDINATORS / NODAL OFFICERS

Each party shall nominate an authorized Nodal Officer/Coordinator for implementation and coordination of activities under this MoU.

From Major SD Singh University

Authorized Coordinator / Nodal Officer

Major SD Singh University
Kanpur Road, Fatehgarh–Farrukhabad, Uttar Pradesh

From Kreole Biotech Inc.

Authorized Coordinator / Nodal Officer

Kreole Biotech Inc.
Mumbai, Maharashtra

The names and contact details may be communicated separately by each party.

19. VALIDITY

This MoU shall initially remain valid for a period of **Three (03) Years** from the date of signing. It may be renewed or extended with mutual written consent.

20. TERMINATION

Either party may terminate this MoU by giving **30 days 'written notice** to the other party.

However, any ongoing clinical trial, participant-related obligation or regulatory responsibility shall continue to be managed in accordance with the approved protocol, applicable law and separate trial agreement.

21. AMENDMENT

Any amendment, modification or addition to this MoU shall be valid only when made in writing and duly signed by authorized representatives of both parties.

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[Signature]

22. NON-EXCLUSIVITY

This MoU shall be non-exclusive, and both parties shall remain free to enter into similar collaborations with other institutions, universities, hospitals, research organizations or companies.

23. NO EMPLOYMENT OR AGENCY RELATIONSHIP

Nothing in this MoU shall be construed as creating an employer-employee, principal-agent, partnership or joint-venture relationship between the parties.

24. EXPECTED OUTCOME

Through this partnership, Major SD Singh University and Kreole Biotech Inc. shall endeavour to contribute towards:

"Awareness, Prevention, Early Detection, Scientific Research, Appropriate Management and Better Quality of Life for People Living with Arthritis and Musculoskeletal Disorders."

The parties shall work together towards the broader vision of the "Arthritis Free India Initiative", with emphasis on evidence-based education, ethical clinical research, healthy lifestyle, early intervention and community participation.

SIGNED AND ACCEPTED

**For Major SD Singh University
Registrar**

Major SD Singh University
Kanpur Road, Fatehgarh,
Farrukhabad, Uttar Pradesh.

Signature: _____

Date: _____

Seal: _____

Registrar

Major S.D. Singh University
Fatehgarh, Farrukhabad

For Kreole Biotech Inc.

Authorized Signatory

Kreole Biotech Inc.
Raheja Platinum, Sag Baug Road,
Andheri East, Mumbai - 400059
Maharashtra.

Name: _____

Designation: _____

Signature: _____

Date: _____

Seal: _____

Witness-1

Name: Dr. A.K. Bhatnagar

Designation: Dean Ayurveda

Institution: Institute of Ayurveda

Signature: _____

Witness-2

Name: Neha Mishra

Designation: Product manager

Institution: Kreole Biotech

Signature: _____