**Collaborative Research Agreement**

**between**

**Saudi Arthritis Registry (SAR) / Saudi Society for Rheumatology (SSR)**

**And**

**(Name of hospital, City)**

This Collaborative Research Agreement (Research Agreement) is entered into to specify the terms and conditions under which Saudi Society for Rheumatology (here in after jointly referred to as SSR), having an address at PO Box **………** Riyadh, Zip code **………** Kingdom of Saudi Arabia and **…………………………….** Hospital (hereinafter jointly referred to as Participant), having an address at **…………………………….**.SSR and the Participant are sometimes referred to individually as a “Party” and together as the “Parties”, with reference to the following facts:

1. SSR has developed, owns and operates an online platform and database for storage of medical data of various rheumatic diseases, known as the Saudi Arthritis Registry (SAR), which containing information relating to patient clinical data. SAR was founded by Dr. Hanan Mohammad Al Rayes, the president of SSR.
2. SSR has engaged Dr. Hanan Al Rayes, SAR scientific committee and a third-party Software development Company (Vendor) to develop the Registry and software, manage subscriptions to store, and access the Registry data.
3. Participant has expressed an interest in participating in the SAR in accordance with SSR requirements.

Therefore, in consideration of the foregoing and the contained covenants herein, and for other good and valuable consideration, the Parties agree as follows:

**Part A:**

**Participation in SAR:**

SSR grants to Participant access to SAR. Participant shall comply with SSR policies and procedures related to use and access SAR.

Users authorized by SAR committee can upload qualified de-identified data in the SAR.

Vendor shall provide to SAR certain implementation, training and support services as applicable.

Participant agrees to participate in the SAR by transmitting data through a web-based portal designated by SSR/ Dr. Hanan Al Rayes.

Participant shall implement the data collection protocols provided by SAR and pursuant to SSR requirements.

Participant acknowledges and agrees that the Participant data stored in the SAR will only include de-identified data.

Participant takes all steps to avoid the submission of duplicative data for inclusion in the Registry. Furthermore, if applicable, Participant takes full responsibility for the acts and omissions of involvement in the Registry.

Participant agrees that it is Participant’s responsibility to obtain any permissions required in order to submit such data for inclusion in the Registry.

Participant will receive the Registry dashboard; standard Registry reports as determined and distributed by SAR; and other reports as SAR may prepare for Participants.

Registry-generated reports may at SAR’s discretion, be structured to reflect data of the Participant, as requested by Participant in writing to SAR committee.

All of the Participant data shall remain the Participant’s property, and SAR will only use it in accordance with the provisions of this Agreement.

It is agreed that once data submitted to the SAR, the return of the Participant’s individual data, is infeasible, as it will have been integrated into the Registry.

Participant agrees that all data submitted by Participant to SAR for purposes of inclusion in the Registry may be used by SAR as a part of the Registry and any subset thereof that SAR may choose to create and use as it sees fit for research by SAR and others authorized by SAR, and the other interests of the Registry (including publication of such data); provided, that no such data shall be used and disclosed in such a way as to identify Participant or any individual physician or physician group, unless and until Participant advises SAR in writing that it has authorized or secured appropriate consent for such disclosure.

Participant acknowledges that SSR is and shall be deemed the owner of all rights to the Registry (including the aggregate data contained therein and subsets thereof), any and all reports based thereon, all information derived therefrom).

Participant may not use SAR Intellectual Property without first obtaining the express written consent of SAR, provided that Participant may use aggregated data from the Registry that have been included in SAR reports to Participant or previously released to the public by SAR.

**Part B:**

**Research Project:**

The ownership and custody of the protocol and research data are retained to SSR. Furthermore, SAR scientific committee reserves the right to produce, disseminate, and revise the data elements, definitions and formats when deemed necessary. However, data of participating center will be owned by the participating center only. No parties have the right to access these data without prior permission of the Participant.

Participant can access SAR data following a collaborative research proposal review and approval of the relevant institutional Research Review Committees and SAR scientific Research Committee and sign a data release consent form.

Therefore, SAR scientific committee and Participant agree to conduct a Research project entitled: “**…………………………….…………………………….…………………………….…………”**

1. Statement of Work:

SAR scientific committee undertakes to conduct the collaborative research described in the attached Appendix A, SSR Statement of Work”, and will furnish the facilities necessary to carry out such Research. Participant undertakes to conduct the research described in the attached Appendix B, ……………………………. Hospital Statement of Work, and will furnish the facilities necessary to carry out such Research.

1. Principal Investigators and Authorship:

### If the collaborative research is initiated by SAR member, the collaborative research will be under the direction of ……………………. as Principal Investigator, who shall be responsible for the overall technical, scientific and programmatic aspects of SSR Research as well as for the coordination of research performed at the various study centers participating in this project. The participating hospital research will be under the direction of Dr. ……… who shall be responsible for the overall technical, scientific and programmatic aspects of the participating hospital.

### Principal Investigator will be the corresponding author and the first name unless he/ she prefers to be the last. Other participants will be co-authors and their names will be arranged according to the number of enrolled patients (minimum 100 patients) from their hospitals.

### If the collaborative research is initiated by SSR member, upon the acceptance and approval by SAR committee, he/ she, at minimum, assume all those responsibilities assigned to Principal Investigator by the relevant regulations governing the conduct of clinical investigations.

### Principal Investigator is encouraged to publish the results of their research. SSR should be acknowledged in all published materials that generated from SAR.

### Principal Investigator, in consultation with SAR/SSR, is free to arrange for copyright when publications or similar materials are developed from work under this Agreement.

**Independent Analysis; Publication.**

Participant may perform his/ her own independent analysis of any of the Participant’s data, and may publish or otherwise present the results of that analysis, so long as such analysis is based upon Participant data alone and does not include aggregate or de-identified data of other Participants. However, Participant is encouraged to acknowledge SAR.

Both Parties shall, where appropriate, comply with the terms of this Agreement, International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines and applicable law.

**Change of PI:**

Each party shall promptly advise the other if for any reason the PI ceases to be available to work on the research project. If both Parties cannot agree on a qualified replacement investigator, either party may terminate this agreement on 30 days written notice to the other.

1. Period of Performance:

The duration of this collaborative research is expected to be …….......… following review and approval of the relevant institutional Research Review Committees.

1. Total Estimated Costs:

Each participating hospital is responsible for covering their individual costs. However, SSR may provide funding for the protocol in accordance to the SSR research committee advice. Participating investigators are also entitled to all trainings, that are in line with this protocol study.

1. Obligations of Confidentiality:

SSR acknowledges that the data submitted to the SAR by Participant are deemed confidential. Accordingly, SAR agrees and acknowledges that it will require SAR’s Vendor to treat such information as confidential. Each Party must maintain the other Party’s Confidential Information in strict confidence, and agree to comply with the privacy and security regulations declared under the guidelines and law of Kingdom of Saudi Arabia.

**Termination:**

Either Party may terminate this Agreement upon 30 days written notification to the other. Termination or cancellation of this agreement shall not affect the rights and obligations of the Parties accrued prior to termination, and to the clauses that by nature extend beyond the termination date of the agreement.

No provision of this Agreement shall be deemed waived and no breach excused, unless such waiver or consent shall be in writing and signed by the Party claimed to have waived or consented.

1. Modifications:

The Registry is a newly developed service of the SSR and, as such, may be subject to modification by SAR committee.

SAR may, from time‐to‐time, modify or amend the substantive provisions of this Participation Agreement related to the manner in which the Registry operates, so long as such modifications or amendments are of general applicability to all similarly situated participants in the Registry.

Participant will be bound by any modifications or amendments to this Participation Agreement unless, within 30 days of receipt of such modification or amendment, Participant notifies SSR that a specific modification or amendment is not acceptable to him/ her, in that case, this Participation Agreement in the Registry will terminate effective at the end of the 30 day period in which SAR/ SSR receives such notice.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

**SAR/ SSR**

By: \_Dr. Hanan Mohammad Al Rayes\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Authorized Representative

SAR/ SSR

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

Participant

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

Authorized Representative

(Printed Participant name)

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

Principal Collaborative Investigator

**Appendix A – SAR/ SSR Statement of work**

(Needs to be filled in – take info from proposal – specify what will be done by ( SAR / SSR )

**Appendix B – Participant Statement of work**

(Needs to be filled in – take info from proposal – specify what will be done by Participant)