

# **IRAn Primary Sjogren Syndrome Registry (IRAPSS)**

## **Memorandum of Understanding**

11 August 2021 – 11 August 2022

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# IRAn Primary Sjogren Syndrome Registry (IRAPSS)

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### Introduction:

IRAn Primary Sjogren Syndrome Registry (IRAPSS) that has been designed and launched by Guilan Rheumatology Research Center in Guilan University of Medical Sciences (Rasht, Iran), approved at 2020 - 1 - 18 (approval ID is IR.GUMS.REC 1398.475.). The main IRAPSS aims are improvement of care of patients with primary sjogren syndrome and establishment a standardized data bank for creating high level evidences. IRAPSS main domains are:

- Demographics/characteristics
- Primary Sjogren syndrome classification criteria
- Disease related quality of life
- Disease activity
- Disease damage
- Treatments

IRAPSS registry master files is included (Described in IRAPSS protocol):

- Protocol
- Patient and work flow
- Data dictionary
- Strategic plan
- Conflict of Interest form
- Memorandum of understanding
- Domains
- Data Flow
- Data Map
- Classification criteria form
- Paper clinical forms
- Paper abstraction forms
- Paper and excel quality assessment forms
- Scan of all RMP paper documents
- SPSS/STATA
- IRAPSS web site (under construction)

### Intellectual property:

All IRAPSS forms, excels, SPSS/STATA and patient source documents are confidential. Mashhad IRAPSS site owns its data and also transfer any intellectual property or their other

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rights to IRAPSS executives as IRAPSS developer. Other IRAPSS collaborators have only access to Mashhad site data through Mashhad executive permission, Dr. Zahra Mirfeizi.

### **Steering Committee:**

We are deeply honored that Dr. Zahra Mirfeizi has accepted to be a member of IRAPSS steering committee.

### **Research Projects:**

- ❖ Executives of IRAPSS Registry, Prof. Asghar Hajiabbasi (ASHA) and Dr. Pooneh Ghavidel Parsa (POGH) will be in list of authors of all articles that have been derived from IRAPSS data.
- ❖ In articles that are derived from Mashhad IRAPSS data, role of ASHA and POGH will be determined by Dr. Zahra Mirfeizi.
- ❖ If only Mashhad IRAPSS data is used for a research project, Dr. Zahra Mirfeizi as first author is responsible for determining list and role of other authors.
- ❖ If Mashhad data are used for a multisite IRAPSS research project (After getting permission of Dr. Zahra Mirfeizi), Dr. Zahra Mirfeizi and persons who he declares, will be listed as Mashhad authors in derived articles. In these articles, first and correspond authors will be determined as consensus by all site executives.

### **Central IRAPSS Site Responsibilities:**

1. Selecting IRAPSS domains and defining IRAPSS outcomes
2. Providing and updating IRAPSS protocol
3. Providing IRAPSS strategic plan
4. Providing and updating case report forms, patient and work flow, data flow, data map, data dictionary, conflict of interest form, memorandum of understanding form and IRAPSS quality assessment forms
5. IRAPSS web site (under construction)
6. Providing central site simulation sessions
7. Helping to Mashhad site through assessing "Mashhad quality assessments" that will be done by Mashhad site coordinator

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## Mashhad IRAPSS Site Responsibilities:

Monitoring of Mashhad site and reporting its quality (Described in the IRAPSS protocol)

## Termination:

This agreement enters into force on 11 August 2021 and will be expired by 11 August 2022. IRAPSS executives are interested in a long term collaboration and this agreement can be continued after evaluation Mashhad quality assessment reports and its Registry Master File (including patient source documents) by IRAPSS central site (Described in the IRAPSS protocol).

Central IRAPSS Executives

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