****

**SOUMISSION DE PROJET DE RECHERCHE**

**COHORTE DESIR – SFR**

**SUBMISSION OF RESEARCH PROJECT**

**DESIR COHORT – SFR**

**TITLE OF THE PROJECT :**

**PRINCIPAL INVESTIGATOR OF THE PROJECT**

**First name/Family Name:** **Birth date:**

**Personal address:**

**Phone number: Fax: Email:**

**Position:** 🖵**Professor** 🖵**Staff doctor** 🖵**Associate professor** 🖵**Assistant professor** 🖵**Fellow**

🖵**Other (Please specify)**

**Administrative membership of the laboratory:**

 🖵**University** 🖵**INSERM** 🖵**CNRS** 🖵  **Hospital** 🖵  **Other**

**Clinical research unit (DRCI) contact:**

**Address:**

**Name of the person in charge:**

**Phone number: Fax: Email:**

**SHORT CV OF THE PRINCIPAL INVESTIGATOR OF THE TEAM:**

(Please provide the medical and/or scientific degree course, current position, and awards or grants…)

**Abstract:**

**Scientific background and rationale**

**Aim**

**Description of the project methodology**

**Expected results**

**References (Optional)**

\* Ethic committee agreement:  Not justified

  Obtained through DESIR cohort agreements

  Need for a new agreement

**Detailed scientific en technical description of the project :**

Plan

► Title of the project

► Background

► Specific aims of the project

► Description of the research project (Patients, technical aspects, methodology)

► Expected results and potential impact

► Schedule

(To follow with10 pages at most)

**TASK OF THE PRINCIPAL INVESTIGATOR AND CONTRIBUTION OF EACH PARTNER:**

(Task of each partner)

► **Principal investigator:**

**► Partners (optional):**

**PUBLICATIONS OF THE PRINCIPAL INVESTIGATOR:**

**► 5 Main publications:**

**► Publications linked to the theme of the project:**

**ESTIMATED BUDGET FOR THE RESEARCH PROJECT:**

**1. Total budget:** **Estimated duration of the project (years):** ……

► **Equipment costs:**

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

► **Operating costs**:

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

► **Salary / grants:**

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

**2. Budget obtained with other Institutions:**

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

**3. Budget requested through other institutions:**

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

 …………………………………………………………………………………………………………………………………

**DATA WHICH ARE NECESSARY FOR THE COMPLETION OF THE RESEARCH PROJECT:**

**Which data do you need?**

 **NUMBER OF PATIENTS:** …… ……………

For the two tables below, check the appropriate boxes matching your request:

* Database file type :

|  |  |
| --- | --- |
| SAS |  |
| CSV |  |

* Needed set of variables (please find the index attached):

|  |  |  |
| --- | --- | --- |
|  | **THEME** | **VISIT** |
| **M0** | **M6** | **M12** | **M18** | **M24** | **M36** | **M48** | **M60** | **M72** |
| **CRF** | Cohort characteristics |  |  |  |  |  |  |  |  |  |
| Disease history |  | NA | NA | NA | NA | NA | NA | NA |  |
| Treatment |  |  |  |  |  |  |  |  |  |
| Comorbidities and medical history |  |  |  |  |  |  |  |  |  |
| Demographic and medico-economic data |  |  |  |  |  |  |  |  |  |
| Disease activity |  |  |  |  |  |  |  |  |  |
| Function |  |  |  |  |  |  |  |  |  |
| Quality of life |  |  |  |  |  |  |  |  |  |
| Clinical exams |  |  |  |  |  |  |  |  |  |
| Diagnosis |  |  |  |  |  |  |  |  |  |
| Laboratory analysis |  |  |  |  |  |  |  |  |  |
| X-Rays (local reading) |  | NA |  | NA |  | NA | NA |  | NA |
| MRI (local reading) |  | NA |  | NA |  | NA | NA |  | NA |
| Sonography |  | NA |  | NA |  | NA | NA |  | NA |
| Bone densitometry |  | NA |  | NA |  | NA | NA |  | NA |
| Classification criteria |  |  |  |  |  |  |  |  |  |
| HS-CRP |  | NA | NA | NA | NA | NA | NA | NA | NA |
| DKK1 baseline |  | NA | NA | NA | NA | NA | NA | NA | NA |
| SOST baseline |  | NA | NA | NA | NA | NA | NA | NA | NA |
| Vitamin D |  | NA | NA | NA | NA | NA | NA | NA | NA |
| Periostin |  | NA | NA | NA | NA | NA | NA | NA | NA |
| Cytokines |  | NA | NA | NA | NA | NA | NA | NA | NA |
| **Central reading wave 1** | mNY sacroilitis  |  | NA | NA | NA | NA | NA | NA | NA | NA |
| BASRI hip |  | NA | NA | NA | NA | NA | NA | NA | NA |
| mSASSS |  | NA | NA | NA | NA | NA | NA | NA | NA |
| MRI sacroiliac joints inflammation score SPARCC |  | NA | NA | NA | NA | NA | NA | NA | NA |
| Mechanical structural lesions |  | NA | NA | NA | NA | NA | NA | NA | NA |
| **Central reading wave 2** | BASRI hip |  | NA |  | NA |   | NA | NA | NA | NA |
| mNY sacroiliitis |  | NA |  | NA |   | NA | NA | NA | NA |
| Grading of sacroiliitis  |  | NA |  | NA |   | NA | NA | NA | NA |
| mSASSS  |  | NA |  | NA |  | NA | NA | NA | NA |
| Presence of at least one syndesmophyte |  | NA |  | NA |   | NA | NA | NA | NA |
| Spine inflammatory yes if at least 5 inflammatory lesions |  | NA |  | NA |   | NA | NA | NA | NA |
| MRI Spine Inflammation score BERLIN |  | NA |  | NA |   | NA | NA | NA | NA |
| MRI Spine Inflammation score SPARCC |  | NA |  | NA |  | NA | NA | NA | NA |
| MRI Sacroiliitis according to ASAS definition |  | NA |  | NA |  | NA | NA | NA | NA |
| MRI Sacroiliac Joints Inflammation score (SPARCC) |  | NA |  | NA |  | NA | NA | NA | NA |
| **Central reading wave 2** | MRI SIJ chronic ≥ 3 fatty lesions |  | NA |  | NA |  | NA | NA | NA | NA |
| MRI SIJ chronic ≥ 3 erosions |  | NA |  | NA |  | NA | NA | NA | NA |
| MRI SIJ chronic ≥ 5 structural lesions (either erosions or fatty) |  | NA |  | NA |  | NA | NA | NA | NA |
| MRI Spine Chronic ≥ 5 fatty lesions |  | NA |  | NA |  | NA | NA | NA | NA |
| **THEME** | **VISIT** |  |
| **M0** | **M6** | **M12** | **M18** | **M24** | **M36** | **M48** | **M60** |  |
| **Central reading wave 3** | BASRI hip |  | NA | NA  | NA |   | NA | NA |  | NA |
| mNY sacroiliitis |  | NA | NA  | NA |   | NA | NA |  | NA |
| Grading of sacroiliitis  |  | NA | NA  | NA |   | NA | NA |  | NA |
| mSASSS  |  | NA | NA  | NA |   | NA | NA |  | NA |
| Presence of at least one syndesmophyte |  | NA | NA  | NA |   | NA | NA |  | NA |
| Spine inflammatory yes if at least 5 inflammatory lesions |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI Spine Inflammation score BERLIN |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI Spine Inflammation score SPARCC |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI Sacroiliitis according to ASAS definition |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI Sacroiliac Joints Inflammation score (SPARCC) |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI SIJ chronic ≥ 3 fatty lesions |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI SIJ chronic ≥ 3 erosions |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI SIJ chronic ≥ 5 structural lesions (either erosions or fatty) |  | NA | NA  | NA |   | NA | NA |  | NA |
| MRI Spine Chronic ≥ 5 fatty lesions |  | NA | NA  | NA |   | NA | NA |  | NA |

**BIOLOGIC DATA (stored serum, DNA, RNA, urine)**

***IMPORTANT: A wrong justification of the requested quantities/volumes could compromise the acceptation of the scientific project***

 **🖵 Serum**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Visit** | **M0** | **M6** | **M12** | **M24** | **M60** |
| **Volume requested :** |  |  |  |  |  |

 **Justification  :** ……………………………………………………………………………………………………………………… ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

 **🖵 DNA**

Quantity requested: …… ……………

**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

 **🖵 RNA**

Quantity requested: …… ……………

**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**🖵 Urine**

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit** | **M0** | **M24** | **M60** |
| **Volume requested :** |  |  |  |

**Justification**: ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**RADIOLOGIC DATA (stored images)**

***IMPORTANT: A wrong estimation of the requested number of patients with radiological data could compromise the acceptation of the scientific project***

***IMPORTANT: Checking one of the following boxes will mean that you require the original CDs of the films in order to perform yourself the reading***

**🖵 Radiological data (X-rays)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Visit** | **M0** | **M12** | **M24** | **M60** |
|  |  |  |  |

**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**🖵 MRI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Visit** | **M0** | **M12** | **M24** | **M60** |
|  |  |  |  |

**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**JUSTIFICATIONS FOR USING DATA FROM THE DESIR COHORT**

Please provide the reasons why your research needs to be performed specifically on the DESIR cohort.

**STATING ON HONOUR :**

I, the undersigned ……………………………………………………………, will hereby fulfil the following commitments:

- I accept to sign a convention with the scientific committee from the DESIR cohort

- I will mention the name « DESIR » in the title or subtitle of all publications relaying on DESIR cohort, as well as the names of 2 investigators from DESIR cohort (including one from DESIR cohort board)

- I will address related publications to DESIR board 3 weeks before submission.

**Name of the principal investigator:** **Signature:**