

# **SICCA** *Sjögren's International Collaborative Clinical Alliance*

## **Study Protocol (Limit of 5 pages)**

**Use the following format to present your study plan. Complete in 12-point font only. Please submit electronic copies in .pdf format.**

- 1) **Lay language summary** (provide a one paragraph summary of the study)
- 2) **Background** (a brief description of the rationale for the study including references)
- 3) **Research Question** (Please formulate a specific research question that includes a primary outcome/dependent variable, and one of more predictor/independent variables – e.g., is there an association between variable(s) X, Y, Z, and outcome W in a defined subgroup of the SICCA cohort)
- 4) **Hypothesis** (Please state the hypothesis behind your research question)
- 5) **Study design** (While the SICCA study design is a prospective cohort study with participants seen a 2 time points, you may wish to conduct a nested study with a different design such as a nested case-control study or other. Please specify your study design, and how it can be adapted to the SICCA cohort)
- 6) **Study population** (SICCA is a well defined population of adult men and women, from various countries and continents, with signs and symptoms that may be suggestive of Sjögren's syndrome. However, you may wish to identify a target population that would be a sub-group within the SICCA cohort. Please define the target population to whom you wish to be able to infer your study results. Please review Case Definition based on the new American College of Rheumatology Classification Criteria for Sjögren's syndrome (Shiboski et al, 2012) on the following page)
- 7) **Variables and Measures, including laboratory assays** (Please define each outcome and predictor variable you wish to include in the analysis you will perform to answer your research question. A list of available variables can be derived from the data collection forms on the SICCA website. If your proposal includes new assays to be performed on SICCA specimens, please describe each assay and the variable that would result from each assay – e.g., assay X will be defined as a continuous variable expressed in mg/mL).
- 8) **Statistical analysis plan and sample size justification/power calculations** (This section should include a plan of the statistical analyses proposed for this protocol. The sample size calculation should include an expected effect size the applicant wishes to detect with a justification on how this effect size was determined, the level of significance (alpha), whether a 1 or 2 sided test will be used, and the desired level of power for the analysis; 80% is standard).
- 8) **QA/QC procedures** (for studies generating new laboratory data, summarize laboratory QA/QC procedures, participation in recognized program, past publication, etc., relevant to the proposed investigations or testing)
- 9) **Timeline** for completion of study (include manuscript preparation and publication)

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## 10) **Cited References**

11) Please submit a copy of your **NIH style biosketch** (go to <http://grants.nih.gov/grants/funding/phs398/phs398.html>) and **Other Support** with publications listed that are relevant to this proposal and SICCA's objectives .

12) **Existing or potential funding source, please specify:** pending application, planned application or funded project, and dates of funded period.

13) If you are requested to submit a revised application please summarize the changes you made and show revisions in your revised application.

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**SJÖGREN'S SYNDROME PROVISIONAL CASE DEFINITION:** based on the new American College of Rheumatology Classification Criteria for Sjögren's syndrome (Shiboski et al, 2012)\*

A "case" is defined as having two out of three of the following objective tests:

- Serology positive for anti-SSA and/or SSB antibodies **OR** (positive rheumatoid factor **and** ANA titer  $\geq 1:320$ ).
- Ocular staining score  $\geq 3$
- Presence of focal lymphocytic sialadenitis with a focus score  $\geq 1$  focus/4 mm<sup>2</sup>;

A "control" may be defined as being negative for all objective tests included in the case definition above, however, applicants may also wish to propose an alternative definition for a control in their proposal.

\* Shiboski SC, Shiboski CH, Criswell LA, Baer AN, Challacombe S, Lanfranchi H, *et al.* American college of rheumatology classification criteria for Sjogren's syndrome: a data-driven, expert consensus approach in the Sjogren's international collaborative clinical alliance cohort. *Arthritis Care Res* 2012;64:475-487.