Sjögren's International Collaborative Clinical Alliance (SICCA)
***Biorepository and Data Registry* #HHSN26S201300057C**
SICCA Dissemination Plan
Alternative Review Process

The Alternative Review Process is an expedited mechanism intended for trainees (students, residents, or fellows) and for investigators with NIDCR-funded projects requiring specimens for quality control purposes. All applications will be reviewed by the SICCA Internal Advisory Board (IAB) and then forwarded to the NIDCR Project Officer for approval to allow for expedited review of these applications.

A. Application Preparation

1. The applicant should submit a 1-2 page letter of intent (LOI) to Annie Chou (annie.chou@ucsf.edu) with the following information:

Trainees	**NIDCR-funded projects requiring specimens for quality control purposes**
▪ Name of the Trainee (student, resident or fellow) and Mentor ▪ Location(s) and institution(s) where research will take place ▪ Role that Trainee will play in carrying out research ▪ Research question ▪ Methods ▪ Proposed length of project (i.e. number of months) ▪ Mentor biosketch and Trainee CV ▪ How did you learn of the SICCA Registry?	▪ Name of Investigator ▪ Location(s) and institution(s) where research will take place ▪ NIDCR grant number ▪ Research question ▪ Methods ▪ Proposed length of project (i.e. number of months) ▪ Investigator Biosketch ▪ How did you learn of the SICCA Registry?

2. The LOI will be reviewed by the SICCA Internal Advisory Board (IAB). If the request appears reasonable and the requested data are available, the LOI will be forwarded to the NIDCR Project Officer for approval. If the request does not appear reasonable or the requested specimens and associated data are not available, the applicant will be notified in writing of the basis for non-approval and a revised LOI will be requested. All revisions must show in HIGHLIGHTED font, and a separate point-by-point description of changes made according to the reviewer's comments must be submitted.

3. If the LOI is approved, the trainee and/or investigator should submit a completed SICCA Data Application and Proposal to the SICCA Coordinating Center by downloading the application from the SICCA website https://sicca-online.ucsf.edu/Home/Dissemination, completing the application, and emailing it to Annie Chou (annie.chou@ucsf.edu).

B. Review and Approval of Applications

1. The application will first be reviewed by SICCA staff to ensure that all necessary information is included. If the application is incomplete, it will be returned to the trainee and/or investigator, for completion and re-submission.

2. The SICCA IAB and NIDCR will review the application according to standardized criteria (see example, page 4).

3. SICCA will contact the trainee/investigator regarding the outcome of review (e.g. approval, modification, or disapproval) approximately 12-14 weeks from LOI submission.

4. If revisions are requested, all revisions must show in HIGHLIGHTED font, and a separate point-by-point description of changes made according to the reviewer's comments must be included for resubmission.

5. Data will not be released until documentation of local Institutional Review Board (IRB) approval has been provided.

C. Publication Guidelines

1. **ALL** abstracts and manuscripts **MUST** be submitted to SICCA two weeks before they are submitted to a journal, conference workshop or other meeting. Abstracts and manuscripts will be reviewed for accuracy. Feedback will be given about any factual errors that need to be corrected before publication.

2. All publications and presentations of studies utilizing data must acknowledge the SICCA registry. The suggested statement for acknowledgment is:

Data used in this manuscript is from the Sjögren's International Collaborative Clinical Alliance (SICCA) Biorepository and Data Registry, funded under contract #HHSN26S201300057C by the National Institute of Dental and Craniofacial Research. This manuscript/presentation was prepared using a publicly available SICCA data set and does not necessarily reflect the opinions or views of the SICCA investigators, the NIH or NIDCR.

3. The question of co-authorship (if any) by members of SICCA Coordinating Center and Research Group members will be negotiated individually for each project if these members participated in analyses and writing of the manuscript. Manuscripts resulting from collaborative studies must be reviewed by all SICCA investigators who are co-authors and the NIDCR Program Officer. Sufficient time for revision should be allowed before submission to a journal. Final revisions also must be available to co-authors for review before resubmission.

4. An electronic copy (.pdf) of all published manuscripts should be sent to Annie Chou (annie.chou@ucsf.edu) to provide an archival record of work resulting from the study.

Lead authors are responsible for complying with NIH Public Access Policy, that peer-reviewed manuscripts arising from NIH funding and accepted for publication on or after April 7, 2008 are deposited in PubMed Central (PMC). The PMCID or NIH Manuscript Submission Reference Number (NIHMSID) should be sent to Annie Chou along with two copies of the published manuscript.

5. **Data provided by SICCA is intended *exclusively* for the purpose of performing SICCA-approved research. The data *may not* be shared with other investigators or used for additional projects without the written consent of the SICCA Directors.**

E. Distribution Process

Data – A core dataset with a description of variables will be made available to applicants who have provided a detailed plan of the proposed statistical analysis, and evidence that a statistician will be performing these analyses (biosketch required). The applicant is expected to provide a list of variables required for their proposal. The applicants would also need to be able provide data analyses outputs as needed for quality control by the SICCA Statistical team.

If applicants do not have access to local statistical support, they would need to collaborate with the UCSF SICCA team for analyses to be performed by the SICCA Statistical team.

SICCA DISSEMINATION REQUEST REVIEW FORM (example)

SCIENTIFIC CONCEPT SHEET REVIEW FORM
Submission Type Initial _____ Revised _____
Title of Study:

Investigator/Contact:

IRB Approval
Does this site have IRB/IEC approval? Yes _____ No _____
IRB/IEC approval number: _____
If a foreign institution – what is the FWA number _____

Does this proposal require specimens? Yes _____ No _____

Does this proposal require data? Yes _____ No _____

Reviewer's Name:

Date Completed:

I. GENERAL COMMENTS:	**YES**	**NO**	**N/A; COMMENTS:**
Is the hypothesis clearly defined?			
Is there sufficient background to justify the hypothesis?			
Are the specific aims clearly defined and feasible?			
Are the hypotheses significant?			
Is the study design appropriate?			
Are the methods to be employed appropriate?			
Is the type and volume of specimen requested appropriate for the methodology suggested?			

Do the aims and importance of the study justify the use of SICCA biospecimens and data? Is the time frame realistic?			

II. COMMENTS:

Issues to be addressed by the proposing investigator

III. SCORE	**IV. RECOMMENDED ACTION**
1	**Approve** with no changes
2	Approve with **minor changes** (comments required)
3	**Major revision required** (to be returned to author and re-submitted)
4	**Reject**