Sjögren's International Collaborative Clinical Alliance (SICCA)
***Biorepository* #HHSN26S201300057C**
SICCA Dissemination Plan

Applications will be reviewed 3 times per year, according to the following schedule:

Application Cycle	Letter of Intent (LOI) Deadline	Approximate Review Completion Date
1	February 1	May 1
2	June 1	September 1
3	October 1	January 1 (of next year)

A. Letter of Intent

The applicant should submit a 1-2 page letter of intent (LOI) to Danielle Drury (danielle.drury@ucsf.edu) with the following information:

1) Name of the PI and Co-PIs (where applicable)
2) Location (s) and institutions (s) where research will take place
3) Hypothesis, specific aims, and *brief* relevant background and significance
4) Requirements for the types and numbers of specimens and associated data
5) Will you need analysis support from the SICCA team?
6) Existing or future support for conduct of the research
7) How did you learn of the SICCA Registry?

2. The LOI will be reviewed by the SICCA Project Directors. If the request appears reasonable and the requested specimen type and number and associated data are available, the LOI will be forwarded to the NIDCR Contracting Officer's Technical Representative (COTR) for approval. If the LOI is approved, the investigator will be contacted within 4 weeks to submit a full application (documents are posted on the SICCA website). 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.

B. Full Application

Two weeks from the date the LOI is approved, a completed SICCA Full Application should be submitted to the SICCA Coordinating Center using the following application forms from the SICCA website:
https://sicca-online.ucsf.edu/dissemination
SICCA Agreement Form

SICCA Application Cover Sheet
SICCA Dissemination Study Protocol
SICCA Data Request Form (*if applicable*)
SICCA Specimen Request Form (*if applicable*)

The completed application should be emailed to Danielle Drury (danielle.drury@ucsf.edu).

C. 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 lead investigator, for completion and re-submission.

2. The SICCA Directors will review the application and assign two members of the International Review Panel to review the application. If the application requires modification, the applicant(s) will be contacted and the application will need to be resubmitted. A third reviewer maybe contacted if there is disagreement between the two reviewers.

3. 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.

4. The reviewers will use standardized criteria (draft form is on page 5 and 6) for evaluation.

5. After receipt of the reviewer's comments, the application will be forwarded to the NIDCR COTR for final approval. Ultimate authority for approval rests with the SICCA Directors and Project Officer.

6. SICCA will contact the lead investigator regarding the outcome of review (e.g. approval, modification, or disapproval).

7. Specimens or data will not be released until documentation of local Institutional Review Board (IRB) approval has been provided along with a Federal wide Assurance (FWA) number for foreign collaborators and a signed and approved MTA agreement (see section D, below).

D. Publication Guidelines

1. **ALL** abstracts and manuscripts **MUST** be submitted to the SICCA Directors 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 samples and/or data must acknowledge the SICCA registry. The suggested form for acknowledgment is:

Data and specimens used in this manuscript are from the Sjögren's International Collaborative Clinical Alliance (SICCA) Biorepository, 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. 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 of all published manuscripts should be sent to Danielle Drury (danielle.drury@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. **Specimens or data provided by SICCA are intended *exclusively* for the purpose of performing SICCA-approved research. These specimens and data *may not* be shared with other investigators or used for additional projects without the written consent of the SICCA Directors.**

E. Material Transfer Agreement (MTA)

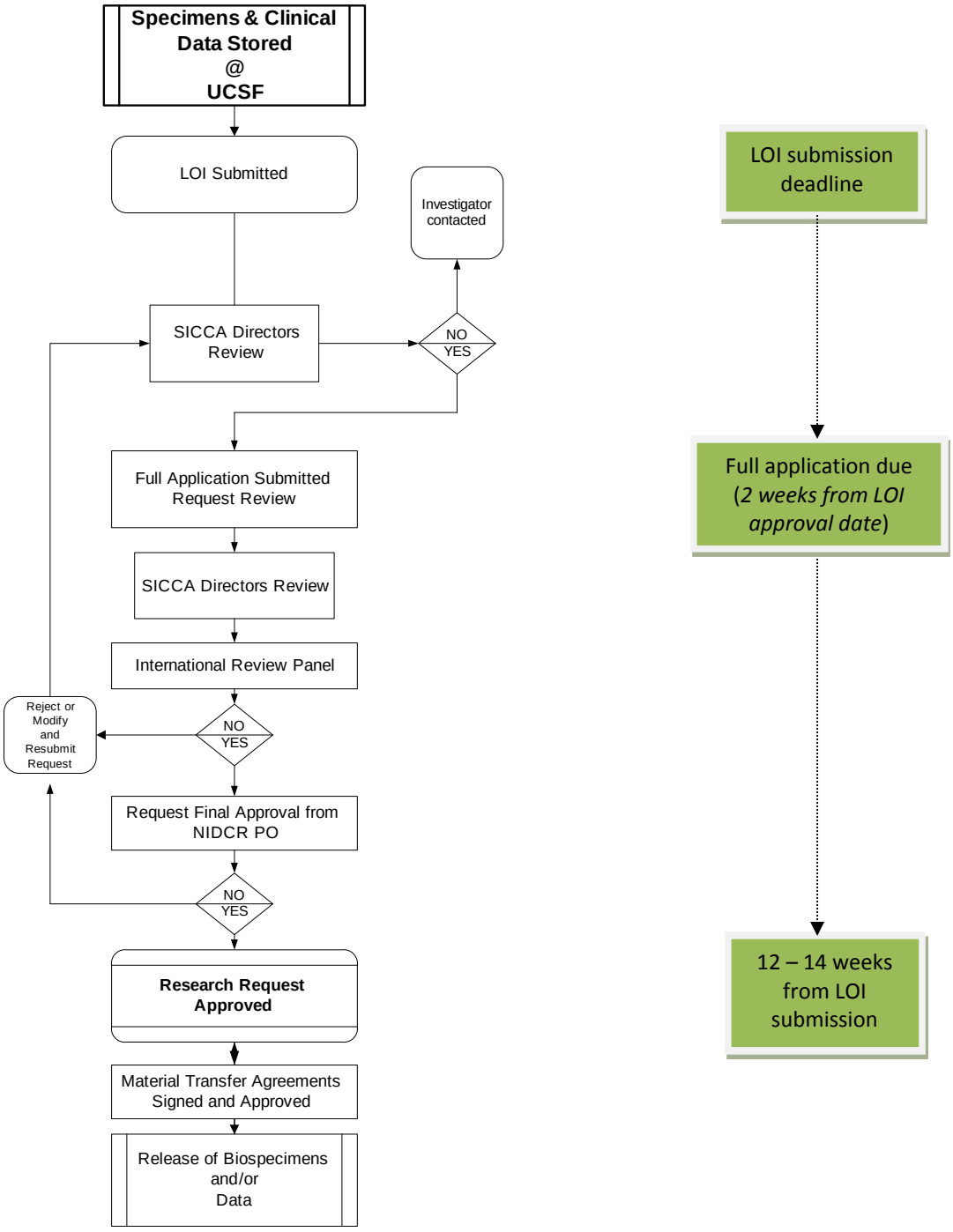
1. Danielle Drury will contact the PI of this application to fill out a MTA questionnaire.

2. The MTA questionnaire is submitted to UCSF's Office of Sponsored Research (OSR).

3. A representative from OSR will contact the applicant and forward a copy of the Simple Letter Agreement (SLA) for Transfer of Non-Propriety Biological Material for signature. Along with the SLA a SICCA agreement form will be sent for the applicant's (PI) signature.

A process flow chart for the dissemination plan follows.

Dissemination Plan Flow Process



SICCA DISSEMINATION REQUEST REVIEW FORM FOR
UCSF SICCA DIRECTORS AND INTERNATIONAL EXTERNAL REVIEWERS

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**

F. Distribution Process

Specimens - The SICCA Repository staff will receive the approved request for specimens and make arrangements with the receiving laboratory to ensure they are ready to receive specimens.

Material Transfer Agreements (MTAs) must be on file with UCSF's Office of Sponsored Research. The MTA is comprised of a simple letter agreement (SLA) that UCSF's Office of Sponsored Research and the recipient or their institute's contract officer must sign. To expedite this process, SICCA staff will complete an MTA questionnaire for each request and email it to UCSF's Office of Sponsored Research.

All specimens with the exception of DNA will be shipped from the SICCA Repository. The UCSF DNA Bank is responsible for extracting DNA from whole blood and shipping the samples to the investigator. During subsequent phases of the dissemination plan DNA samples from blood relatives collected using Oragene collection kits will be made available.

All specimens will be shipped on dry ice with the exception of paraffin slides. The UCSF SICCA Repository staff are trained and certified to ship specimens worldwide on dry ice. They have been trained according to IATA regulations. The investigator will provide the SICCA Repository with a Federal Express account number to pay for all shipping charges.

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.

G. Expenses

There are expenses that will be generated due to the dissemination of specimens and data, which will be the responsibility of the investigator.

Examples of these expenses are:

- Preparation and shipment of specimens by SICCA Repository (charges will apply based on the number of specimens requested)
- DNA normalization and aliquoting if investigator requires a format other than a 96 well plate

- Shipments of DNA
- Paraffin or cryosectioning of LSG specimens