Researcher Data Access Form & Data Use Agreement

First Name: _____

Last Name: _____

Organization: _____

Professional Title:_____

Work Address: _____

E-mail: _____

Phone: _____

Cell phone: _____

Fax: _____

Project Proposal: The investigator must provide an electronic copy of IRB approval (unless general data is requested), a study proposal including the specific aims of the study, the name and qualifications of the investigator(s), the research center, and in the case of a clinical trial, a description of the procedures that will protect the confidentiality and security of Registry participants and a sample study recruitment letter and consent form. The rationale for selection of the population inclusion and exclusion criteria should be described in the project proposal.

The list of the team of researchers involved in the study and their qualifications for this project should accompany the proposal.

Describe the data you are requesting:

Attached IRB approval: yes/no

I agree with the terms of the Researcher Access to Data Policy.

Signature: _____

Date: _____

Email to: Christopher L. Bowlus at clbowlus@ucdavis.edu and

cc: contactus@pscpartners.org and registrycoordinator@pscpartners.org

Researcher Access to Data Policy

Introduction

The PSC Partners Patient Registry (Registry) was created to facilitate and accelerate primary sclerosing cholangitis (PSC) research towards developing new treatments and a cure for PSC. It is a PSC patient-driven international registry serving the PSC patient, physician, and research communities by helping foster a better understanding of PSC.

PSC Partners Seeking a Cure (PSC Partners) is committed to providing investigators and industry an opportunity to access Registry data and to assist in study recruitment while maintaining subject privacy.

Participation in the Registry allows patients to be informed about opportunities to participate in clinical studies and to be kept up-to-date on the progress of PSC studies and clinical trials.

Four (4) types of requests can be made to the Registry. 1. For recruitment to clinical trials or other clinical studies, the Registry curator can perform queries based on the inclusion/exclusion criteria of a study and send potential subjects information about a study for which they may qualify. Registry participants may choose to contact the investigator and/or industry sponsor. Final determination of study qualification will be determined by the investigator and/or industry sponsor. 2. For data analysis, current Registry data, stripped of personal identifiers, can be provided to a researcher. 3. For surveys that are exempt from informed consent as determined by the researchers' Institutional Review Board, the Registry curator can send surveys or links to surveys to participants of the Registry. 4. For each survey question on the registry, graphs of aggregated de-identified data can be made available to the investigator upon request.

PSC Partners Patient Registry Data Access Policy

This policy provides information and guidelines for investigators and industry sponsors wishing to request access to de-identified patient data residing in the Registry. The policy requires of investigators and industry sponsors that the use of the data remains ethical, purposeful and consistent with each original study proposal and access to data request.

In making the data available to investigators, PSC Partners is bound by its responsibility to guard the confidentiality of registry participants.

Requestor's Responsibilities Regarding Data Use

1. The specific purpose for the data use must be agreed to in writing by the investigator and industry sponsor requesting the material and the selected representatives of the PSC

Partners Scientific/Medical Advisory Committee Registry Sub-Committee plus selected representatives of the PSC Partners Board and/or Registry curators (Registry Committee) for the approval of the request.

2. The investigator and the industry sponsor must sign the Data Use Agreement, agreeing to abide by this Data Access Policy.

3. The investigator must provide an electronic copy of an IRB approval or for surveys, IRB exemption (see Levels of Data below), a study proposal including the specific aims of the study/clinical trial and the name and qualifications of the research center. The rationale for selection of the population inclusion and exclusion criteria must be described in the project proposal. Other information may be required as needed by the Registry curator.

4. The investigator and industry sponsor must agree in writing that the data will be used only for the stated purpose and only by the requesting party and may not be passed on or shared with a third party.

a. The Data Use Agreement is not transferrable. Data will not be used to establish the individual identities of any of the subjects from whom data is obtained.

b. Investigator, team, employees, industry sponsors, and other research staff members agree not to transfer data to any other entity or any individual. The investigator will not sell or distribute the data and will only share the data with his/her research staff members who are subject to the terms of the Data Use Agreement.

5. The data may be used only for the time period specified in the approved request. Approval for access to the data will be for an interval of one (1) year from the date of approval. Investigators must re-apply and submit to a progress report annually .

6. The impact of research on people living with PSC should be a key consideration for each project. Best ethical practices for insuring the interest of the patient should be applied.

7. Any publication, oral and written presentations, disclosures, and publications resulting from any and all analyses of the Registry data or based on the Registry data must cite PSC Partners as the source of data, and a copy of the study publication(s) must be sent to PSC Partners within 30 days of publication.

8. Individuals and industry sponsors accessing and using patient data assume full responsibility for any and all uses of such data.

Levels of Data that can be requested by investigators approved by the Registry Committee

1. **Graphs of de-identified aggregated data.** This data can be requested from the Registry Committee at registrycoordinator@pscpartners.org.
2. **Case-by-case de-identified data on a password-protected Excel sheet.** This level of data requires a project proposal, IRB approval or exemption and the approval of the Registry Committee Chair.

3. **Request for additional patient data through emailed questionnaire.** This level of data requires a project proposal, IRB approval or exemption and the approval of the Registry Committee.
4. **Recruitment of registrants for studies and clinical trials**. Request to access individual subjects requires a project proposal, IRB approval, and the approval of the Registry Committee. The Registry curator can perform queries based on the inclusion/exclusion criteria of a study and send potential subjects information about a study for which they may qualify. The Registry may provide the subject/caregiver a recruitment flyer, informed consent form, and/or contact information for the site(s) conducting the study. Personal identifiers or subject contact information will not be provided to investigators. It is up to the consenting registry participants to decide whether to contact the investigator and/or industry sponsor.