

## PARASOL Grant Announcement

### Objectives

The International Society of Glomerular Disease (ISGD) administers a research grant program for the PARASOL project. **PARASOL (Proteinuria and Other Biomarkers as Endpoints for Clinical Trials in Kidney Disease)** is a collaborative international effort that aims to define the quantitative relationships between short-term changes in biomarkers and long-term outcomes in kidney diseases including **FSGS, APOL1 kidney disease, and primary membranous nephropathy (PMN)**. This work supports the investigation of potential clinical trial endpoints as a basis for regulatory drug approval.

The PARASOL program is achieving these aims by conducting large-scale analyses of existing data from patients of all ages with **FSGS, APOL1 kidney disease, and primary membranous nephropathy (PMN)** who have contributed to observational cohort studies, completed clinical trials, regional or national registries, or real-world data sets.

### Eligibility

There are two programs supported under this announcement:

- The **clinician investigator program** is open to all investigators or clinicians who oversee an existing cohort study, registry, or real-world dataset inclusive of substantial FSGS, APOL1 kidney disease, or primary membranous nephropathy (PMN) patient data meeting the dataset eligibility criteria defined by the PARASOL Data Analysis Team.
- The **statistician program** is open to individuals with key expertise in statistical planning and execution that will support the design and conduct of the statistical analysis necessary for one or more PARASOL projects.

### Dataset Eligibility

In order for a dataset to be considered eligible for inclusion in PARASOL, datasets must have (1) an adequate number of patients with a PARASOL disease of focus that can (2) contribute the following data:

Required data elements for all patients regardless of disease state:	
Data element	Timing
Primary kidney diagnosis and method of assignment (e.g., biopsy, genetics, etc.)	Baseline
Age	Baseline
Sex	Baseline

eGFR <sup>^</sup>	Longitudinal*
Urine protein, urine albumin	Longitudinal*
Date of kidney failure, death	Longitudinal
<b>Required data elements on all patients with Membranous Nephropathy:</b>	
PLA2R-Ab (and assay characteristics)**	Longitudinal
<b>Required data elements on all patients with APOL Kidney Disease:</b>	
Number of APOL1 High Risk Alleles	Baseline
Race, ethnicity	Baseline
<sup>^</sup> or components of (i.e., sCr, cystatin C, height) *multiple measurements in 12 month period strongly preferred **existing data is strongly preferred; if not available, datasets with biospecimens that could be tested will be considered.	

## Funding

**ISGD** will award funds in accordance with anticipated costs per project to support high quality dataset contributions and statistical leadership to PARASOL. To protect the integrity of the PARASOL study and ensure regulatory compliance, applying registries and individuals must be reviewed and approved by the PARASOL Organizing Committee before submission of a proposal for funding from **ISGD**.

- Projects will be funded directly by **ISGD** to the recipient institutions.
- Budget and justification will be reviewed by the PARASOL Finance Committee in consultation with the PARASOL Organizing Committee and a decision will be made regarding support needed to ensure high quality registry data is able to be contributed.
- Funds will be provided to cover project **direct costs only. No indirect costs.** **ISGD** has adopted a policy to support direct costs only.
- The number of projects funded will be dictated by the size of project budgets requested and awarded. **ISGD** makes this determination at the time of review.

## Meritorious Characteristics

Proposals will be evaluated for their compliance with the guiding principles described above. The following project characteristics will be considered meritorious if:

1. The proposed project is willing and able to contribute necessary and valuable data or statistical expertise to the PARASOL project to support achievement of PARASOL aims.
2. The proposed project leads can meet the timelines established for PARASOL project success.

## Application/Review Process

The process of submitting applications to **ISGD** for this grant program occurs in 2 steps. No application can be submitted to **ISGD** before approval of/invitation by the PARASOL Organizing Committee, which assesses proposals for feasibility.

1. **PARASOL Organizing Committee Approval:** The investigator meets with the PARASOL intake team to discuss PARASOL objectives and alignment and feasibility of including the proposed registry/dataset. An assessment of contributing registry/dataset value is provided to the PARASOL Organizing Committee. Approval and invitation to submit is necessary prior to submission for funding. Please contact [parasol@is-gd.org](mailto:parasol@is-gd.org) to request a meeting.
2. **Grant Submission to ISGD:** Once the PARASOL Organizing Committee approves the proposed registry/dataset, the investigator will be invited to submit a grant proposal to **ISGD** utilizing the application template provided. **ISGD**, in conjunction with the PARASOL grant review committee, is responsible for funding decisions.

**Deadline:** There is no formal deadline for the application and applications are reviewed on a rolling basis. Applicants may ask questions of the committee prior to making an application by contacting [parasol@is-gd.org](mailto:parasol@is-gd.org).

### Application Format

Applications must be submitted using the PARASOL grant application form:  
<https://is-gd.jotform.com/team/parasol/parasol-grant-application>

### Terms of Support

- Funds (**direct costs only**) are provided to the investigator's institution for use by the applicant; it is the applicant institution's obligation to ensure proper use of funds and timely submission of progress reports. Funds will be provided to cover project direct costs only. No indirect costs. **ISGD** has adopted a policy to support direct costs only.
- Disbursal of grant funds will be made in 2 payments. 50% of payment will be made upon notice of award and the remaining 50% will be paid following either receipt of registry data in the format established by the PARASOL Data Analysis Committee or confirmation by the PARASOL Data Analysis Committee of active participation in statistical planning.
- Principal investigators must comply with human institutional review board requirements and demonstrate current approval of these committees.
- It is expected that data provided to the coordinating center will be shared in accordance with established data use agreements between the registry and the data coordinating center.
- It is expected that publications will be submitted in compliance with the publications policies of PARASOL.
- **ISGD** support will be acknowledged by grantees in publications, presentations, abstracts, and other relevant press releases and on associated websites.
- **ISGD** does not discriminate on the basis of race, gender, religious, or ethnic group; applicants should assure compliance with this policy in designing and executing their studies.