**COVID-19 Global Rheumatology Alliance Protocol**

**Objective:**

This internet-based survey will capture information about COVID-19 cases among patients with rheumatologic and autoimmune diagnoses. Data will be used in quality improvement/surveillance efforts to inform efforts aimed at improving treatment of these patients, including:

* Management of rheumatic and autoimmune diseases in light of the COVID-19 epidemic
* Prevention and treatment of COVID-19 in patients on immunomodulatory medications

**Background and Significance:**

COVID-19 is a novel coronavirus which has caused a WHO-declared pandemic in 2020. Patients with underlying chronic health conditions and who are taking immunomodulatory medications are thought to be at increased risk of poor outcomes. Collecting information about COVID-19 outcomes among patients with rheumatic diseases and on immunosuppressive medications will allow clinicians to provide advice and improve the care of such patients.

**Research Design and Methods:**

Patients with rheumatic and autoimmune conditions who have confirmed or suspected COVID-19 infection will be identified by treating clinicians. De-identified patient data will be entered into a web-based survey developed and hosted by UCSF using the secure REDCAP tool. Data will be hosted on a UCSF server with state-of-the-art data and privacy protection procedures in place. A computer-generated study identifier will be assigned to each patient at the time of data entry. Data to be collected includes information about autoimmune diagnosis, immunomodulatory medications, COVID-19 treatments, and outcomes (see case report form). PHI such as patient names or date of birth will not be collected. Providers entering data into the registry may retain the unique study identifier if they would like to later enter updated case information.

Data will be analyzed for relationships between disease state, medication exposure, and outcomes such as hospital admission, ICU admission, intubation, and death. Care will be taken to account for confounding and to interpret data correctly with respect to correlation and causation.

**Human Subjects**:

This study was determined by the UCSF to be quality improvement/surveillance research, and not human subjects research. Other institutions have reached the same determination or have approved the study as exempt, not requiring consent or HIPAA. These additional approvals are available on the rheum-covid.org website. Given exempt status, individual sites should not need to obtain individual IRB approvals, but should check with their local IRBs if there are more stringent procedures in place locally.

**Potential risks**:

This study poses minimal risk. There is a very small risk of a breach of confidentiality of medical record information and associated privacy, which is mitigated by a) not collecting PHI in the survey, b) assigning a study identifier to each patient.

**Potential benefits**:

We are collecting data with the aim of rapidly improving prevention and treatment of COVID-19 in patients with rheumatic and autoimmune disease. If patients whose data is captured have ongoing COVID-19 related treatment needs when changes to care are implemented, they may receive direct benefit from this study. Otherwise, there will be no direct benefits to patients whose data is captured.

**Secondary and future data uses:**

The de-identified data collected as part of this study will be maintained at UCSF on a secure server and shared in aggregated form with the rheumatology community and with the public. It may be used in other studies performed by the Global Rheumatology COVID-19 Alliance or by contributing organizations to evaluate the relationship between rheumatologic disease, immunomodulatory medications, and health outcomes.

**Dissemination and publication of outcomes**

We anticipate that results will be used to inform national and international practice regarding management of rheumatology patients and immunomodulatory medications, and may ultimately be published in peer-reviewed journals.