# COViMS Protocol

COViMS (COVID-19 Infections in MS & Related Diseases) is a joint effort of the US National MS Society and the Consortium of MS Centers to capture information on outcomes of people with MS and other CNS demyelinating diseases (Neuromyelitis Optica Spectrum Disease, or MOG antibody disease) who have developed COVID-19.

## Objective:

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

- Management of multiple sclerosis 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 multiple sclerosis and on immunosuppressive medications will allow clinicians to provide advice and improve the care of such patients.

## Research Design and Methods:

Patients with multiple sclerosis (MS) who have confirmed or probable COVID-19 infection will be identified by treating healthcare providers. De-identified patient data will be entered into a web-based survey developed and hosted by Washington University (WU) using the secure REDCAP tool. Data will be hosted on a WU 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 MS 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 a copy of the submitted record.

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 Washington University in St Louis IRB to be not human subjects research. The database contains only de-identified data, in accordance with HIPAA Safe Harbor De-Identification standards. Given exempt status, individual reporters 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 MS. 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 WU on a secure server and shared in aggregated form with the MS community and with the public. It may be used in other studies performed by the National Multiple Sclerosis Society or by contributing organizations to evaluate the relationship between MS, 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 MS patients and immunomodulatory medications, and may ultimately be published in peer-reviewed journals.