IRB Minimal Risk Protocol Template

General Study Information

Principal Investigator: Mark Parkulo, MD

Study Title: Seroprevalence of SARS CoV 2 Antibodies in Previously undiagnosed Healthcare Workers

Protocol version number and date: Version 1.0 04/17/2020

Research Question and Aims

Hypothesis: Healthcare workers with suspected COVID-19 exposure and negative test demonstrate seroprevalence of SARS CoV 2 Antibodies.

Aims, purpose, or objectives: To identify healthcare workers with SARS CoV 2 antibodies who have not been previously diagnosed and are presumed COVID-19 negative and determine the level of immunity in this population which could inform further decisions about widespread antibody testing in a healthcare worker population.

Background:
Very little is known about the seroprevalence of SARS CoV-2 Antibodies in a healthcare employee population. Some are recommending antibody testing for healthcare workers on a broad scale to determine immunity. Antibody testing is now available at Mayo Clinic in Florida.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol*.

Healthcare workers in surgical and procedural areas will be contacted to participate in this study. Those employees, who were identified as potentially being exposed to COVID-19 and were screened with PCR testing twice (with negative results), will be asked to participate in this study to check for antibodies presence in their blood. Principal Investigator and Co-Investigators will reach out to those employees and offer them participation in this study. A list of employees will be obtained from the Employee Health and Principal Investigator already confirmed that this list will be available as soon as study is approved by IRB.

Upon agreement to participate in this study, the participants will complete a brief survey (attached).

Responses to questions will be directly entered into REDCap and captured by the study team members.

Study participants will be asked to have a blood test for antibodies performed at Mayo Clinic Florida. Approximately 5ml of blood will be obtained for this test. The charge for this test is being covered by the participants' insurance per CARES Act.

Official letter from Mayo Clinic to Medica included in the IRB application. Per email discussion with Cathryn Fraser, Christina Zorn, and Mark Parkulo, MD, the antibodies testing will be paid for by Medica for employees covered by this insurance.

Should results come back with presence of antibodies; the employees will be notified and instructed to follow up with their PCP. The test is not aimed at detecting presence of COVID-19, only antibodies.

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 300

Subject population (children, adults, groups): Adults

Inclusion Criteria:

- Age ≥ 18 years old
- Mayo Clinic employee in procedural and surgical area
- Suspected COVID-19 exposure
- Completed PCR test twice with negative results

Exclusion Criteria:

- Refusal to participate in this study
- Subject not covered by Medica insurance

Biospecimens

Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.

Volume per blood draw: 5 ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) single draw

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) ___ _____

Prospective collection of biological specimens other than blood: _____ _____

Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

Date Range for Specimens and/or Review of Medical Records:
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

☒ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples
- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement:
This is an exploratory study and power statement is not applicable at this time.

Data Analysis Plan:
Descriptive statistics and mean, median will be reported for the entire data set. The information will be deducted based on the frequency of identified healthcare workers with demonstrated immunity to COVID-19.

Endpoints
Primary:
Secondary: