STUDY PROTOCOL

Project Title: Reducing Spread of COVID-19 in a University Community Setting: Role of a Low-Cost Reusable Form-Fitting Fabric Mask

NCT Number: NCT04979858

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Study Protocol

The primary aim of the proposed research is to test the role of a newly developed reusable form-fitting fabric mask ("Focal Mask") in reducing the spread of COVID-19 in a community setting comprising undergraduate students living in dormitories at Georgia Tech. The study is designed with the corollary aim of assessing the role of wearing any type of face covering in reducing spread in the same community setting. Yet another aim is to assess the social, behavioral, aesthetic, and usability aspects of wearing face coverings in public settings. The subjects will be assigned randomly and equally to the Control and Treatment groups, respectively.

The Study Population and Data Collection: The subject population will comprise 200[1] undergraduate students staying in the dormitories at Georgia Tech, preferably freshmen and sophomores with meal plans. There will be no restriction on race, gender, or sexual orientation for participating in the study. The subject cohort chosen will attempt to reflect the demographics of the undergraduate student body at Georgia Tech. The participating subjects will have the option to withdraw from the study at any time. The recruitment of subjects will be carried out in collaboration with Georgia Tech Housing through e-mail and web announcements. The research team will be accessible to the subjects at all times during the study.

As part of the informed consent process during recruitment, the Treatment Group will be told about the use, care and laundering of the Focal Mask during the study. The planned sample size of 200 accounts for dropouts, which were likely to occur so that a statistically significant sample was present to assess the effect of the mask. A randomized study could not be undertaken for ethical and practical reasons (e.g., the fact that the behaviors of students cannot be controlled leading to heterogeneity).

The study will be spread over six weeks consisting of three phases: Pre-treatment, Treatment, and Post-treatment, with each phase lasting two weeks. The two-week period for each phase was based on the following rationale: The incubation period of COVID-19 virus has been assumed to be five days. About 97% of the people who get infected and develop symptoms will do so within 11 to 12 days, and about 99% will within 14 days, which is the basis for the 14-day quarantine recommended by Centers for Disease Control and Prevention.

The health and well-being of the subjects will be tracked daily during the study. Any student falling sick could seek medical help using the on-campus health services. Georgia Tech's COVID-19 testing capacity was 1,500 tests per day, but could accommodate 3,000 tests per day. If the COVID-19 test were positive, the subject would be excluded from the remainder of the study. Those subjects will also be compensated at the end of the study. Figure 1 shows the study timeline.

[1] 201 subjects ended up being enrolled; the Georgia Tech IRB approved the request to amend the initial IRB application to increase the subject population count from the planned 200 to the enrolled 201.

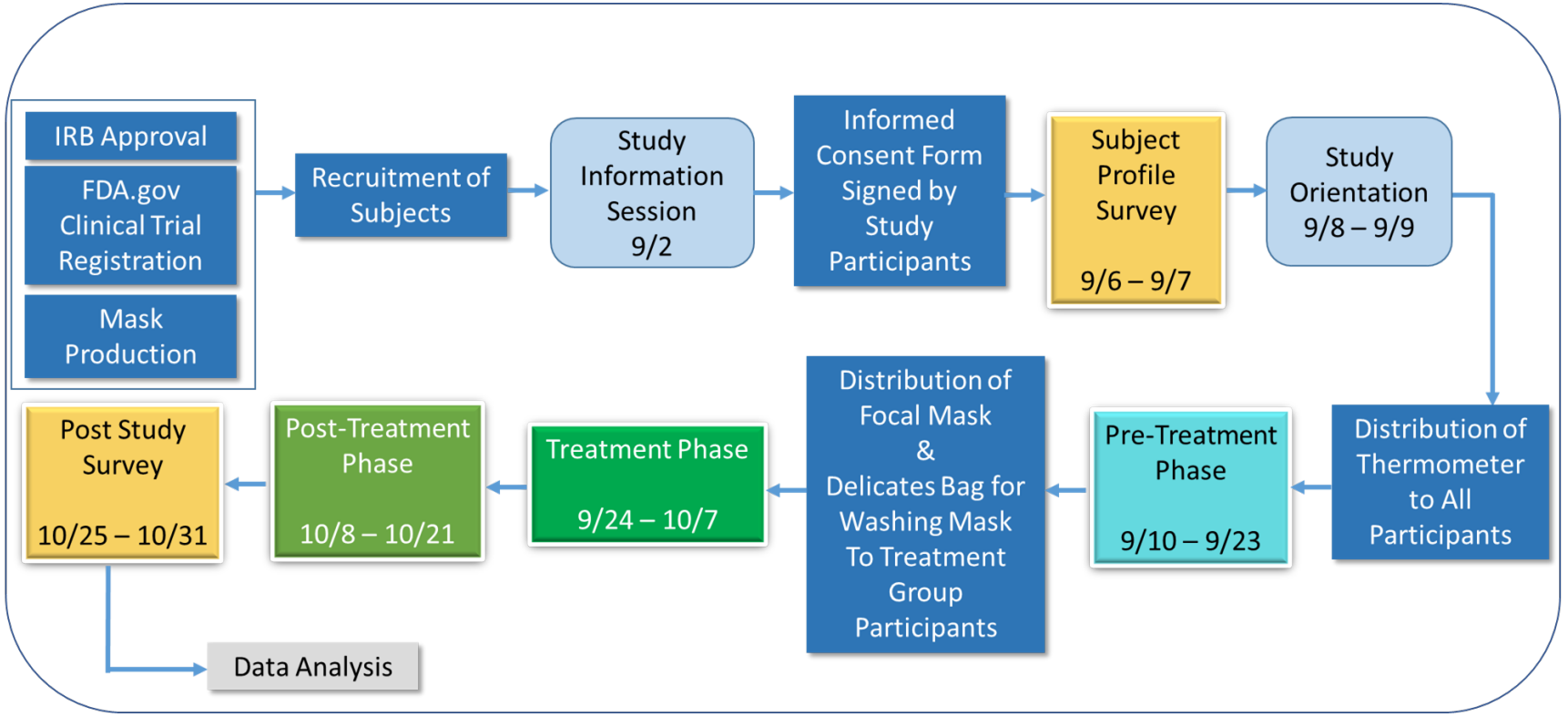

Figure 1. The Human Subject Study: Timeline and Activities

Data Collection: During the study, demographic, behavioral, and mask use data were recorded and appropriately de-identified. No specimens were obtained from the subjects. All the collected data were access limited, and destroyed when no longer needed to perform the study or analysis or after completion and publication of the study, whichever comes first. COVID-19 diagnoses were self-reported by the subjects.

1. At the beginning of the study, each subject provided the following data:
   a) Subject Profile: Demographic information, class schedule, dining plans
   b) Baseline Practice Data: Mask usage practice (type, duration), typical social interactions

2. During the study, each subject provided the following data every day:
   a) Health Metrics: Temperature, Typical COVID-19 symptoms (if any)
   b) Mask Usage Data: Type and duration of mask usage including washing
   c) Activity Data: Classes attended, group meetings, social and dining interactions

3. At the end of the study, each subject provided the following data:
   a) Usability: Comfort, Ease of Donning/Doffing, Impact on Communication
   b) Shape Conformability: Conforms to face, Shape retention after washing
   c) Ease of Care: Ease of washing
   d) Aesthetic and Social Perceptions: Style, Perceptions of others, Impact on personal behavior and degree of social interactions

The statistical analysis involved the use of the single-factor ANOVA test to assess the importance of the various factors associated with the design of the Focal Mask (the Treatment) that would impact its performance in reducing the spread of COVID-19, which is caused by the SARS-CoV-2 virus. The Bonferroni t-test was conducted *post hoc* to assess the statistical significance of the various factors.