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Original Article

The Cabarrus County COVID-19 Prevalence and Immunity (C3PI) Study: design, methods, and baseline characteristics

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Abstract: Objectives: Coronavirus Disease 2019 (COVID-19) is a viral illness with public health importance. The Cabarrus County COVID-19 Prevalence and Immunity (C3PI) Study is a prospective, longitudinal cohort study designed to contribute valuable information on community prevalence of active COVID-19 infection and SARS-CoV-2 antibodies as the pandemic and responses to it have and continue to evolve. We present the rationale, study design, and baseline characteristics of the C3PI Study. Methods: We recruited 1,426 participants between June 2020 and August 2020 from the Measurement to Understand the Reclassification of Disease of Cabarrus/Kannapolis (MURDOCK) Study Community Registry and Biorepository, a previously established, community-based, longitudinal cohort. Participants completed a baseline survey and follow-up surveys every two weeks. A nested weighted, random sub-cohort (n=300) was recruited to measure the incidence and prevalence of active COVID-19 infection and SARS-CoV-2 IgG antibodies. Results: The sub-cohort was younger (56 vs 61 years), had more men (39.0% vs 30.9%), and a higher proportion of Hispanic (11.0% vs 5.1%) and Black participants (17.0% vs 8.2%) compared with the overall cohort. They had similar anthropometrics and medical histories, but a greater proportion of the sub-cohort had a higher educational degree (36.1% vs 31.3%) and reported a pre-pandemic annual household income of >$90,000 (57.1% vs 47.9%). Conclusion: This study is part of a multisite consortium that will provide critical data on the epidemiology of COVID-19 and community perspectives about the pandemic, behaviors and mitigation strategies, and individual and community burden in North Carolina.

Keywords: COVID-19, coronavirus, SARS-CoV-2, methods, study design

Introduction

As of November 1, 2021, the United States has experienced approximately 750,000 deaths [1] and is expected to suffer an immense economic loss due to the Coronavirus Disease 2019 (COVID-19) pandemic [2]. Of these 750,000 deaths, approximately 18,000 were recorded in North Carolina (NC) (https://covid19.ncdhhs.gov/dashboard). The first confirmed case of COVID-19 in NC occurred March 3, 2020 (https://www.ncdhhs.gov/news/press-releases/north-carolina-identifies-first-case-covid-19), and the first confirmed community spread was identified on March 19, 2020 (https://www.wect.com/2020/03/19/first-case-community-spread-covid-confirmed-north-carolina/). Throughout the pandemic, the NC Department of Health and Human Services (NCDHHS) has put into place mitigation strategies,

such as closing private establishments and schools, mask mandates, and stay-at-home orders. As COVID-19 numbers continue to fluctuate, limitations of widespread community testing, in addition to asymptomatic COVID-19 illness and the addition and relaxation of mitigation strategies, contribute to gaps in information about the true community prevalence of COVID-19. Further, serology testing to determine the prevalence of SARS-CoV-2 antibodies has not been readily available. To fully understand the need for disease-mitigating societal restrictions and the vulnerability of the NC population, it is imperative to understand and monitor the ever-changing epidemiology of this disease.

The Cabarrus County COVID-19 Prevalence and Immunity (C3PI) Study complements the NCDHHS' ongoing initiative to stop the spread of COVID-19. This study is part of a collaborative effort among the University of North Carolina at Chapel Hill (UNC-CH), East Carolina University (ECU), and Duke University, supported by the NCDHHS. These partners will conduct a set of related but independent COVID-19 surveillance studies in select NC counties (Chatham [UNC-CH] [3], Pitt [ECU], and Cabarrus [C3PI Study]). We report the design and methods of the C3PI Study. Through the C3PI Study, we will contribute valuable information about community prevalence and durability of SARS-CoV-2 immunity and occurrence of active COVID-19 cases as the pandemic and responses to it have and continue to evolve. This will be achieved through investigating, (1) participant perceptions, concerns, and practices related to the COVID-19 pandemic and its mitigation strategies, 2) change in incidence of COVID-19 infection, and 3) prevalence of SARS-CoV-2 IgG antibodies.

Methods/design

Overall design

The C3PI Study was designed with two components: 1) a baseline survey followed by biweekly follow-up surveys of health, COVID-19 infection status, mitigation and other behaviors, and concerns and impressions about the COVID-19 pandemic (goal recruitment 1,500 individuals); and 2) a nested weighted, random sample (N=300) of participants to undergo biweekly SARS-CoV-2 reverse transcriptase-polymerase chain reaction (RT-PCR) testing, and every other month serum sampling for SARS-CoV-2 IgG antibodies during the initial study period (June 2020-April 2021) and monthly during a study extension (May 2021-December 2021).

Study population

The C3PI Study is nested within the Measurement to Understand the Reclassification of Disease of Cabarrus/Kannapolis (MURDOCK) Study. The MURDOCK Study is an ongoing longitudinal study operated by the Duke Translational Population Health Research Center in the Duke Clinical & Translational Science Institute (CTSI) [4, 5]. Of 12,526 participants recruited into the MURDOCK Study between 2009 and 2016, 10,412 were active at the start of the C3PI Study and considered for recruitment. Individuals not currently residing in NC (n=776) and those with no email address on file (n=2,316) were excluded, leaving 7,320 individuals eligible for recruitment into the C3PI Study (**Figure 1**).

Overall, 1,426 eligible individuals provided consent for the initial phase of the C3PI Study, and 1,019 (71.5%) were re-consented for the study extension. Thirteen (0.9%) consented participants did not complete the baseline survey or any follow-up surveys and were excluded from all analyses. The most complete record was kept for three (0.2%) participants who submitted duplicate enrollments. Thus, the final analysis population included 1,410 participants. Of these, 1,060 (75.2%) expressed interest in testing sub-cohort participation. Those currently residing within the original 20-Zip-Code Cabarrus County catchment area of the MURDOCK Study (n=943) were eligible for the nested testing sub-cohort, and 300 were selected by weighted random sampling.

Recruitment methods

Eligible MURDOCK Study participants received a recruitment email that included a secure link to a Duke REDCap survey. Invitations were open for three months (June 2020-August 2020). Email reminders were sent weekly during the first month, and monthly thereafter. Once in REDCap, participants could review the study synopsis, objectives, and informed consent form, and if interested, provide electronic informed consent to participate. At the time of

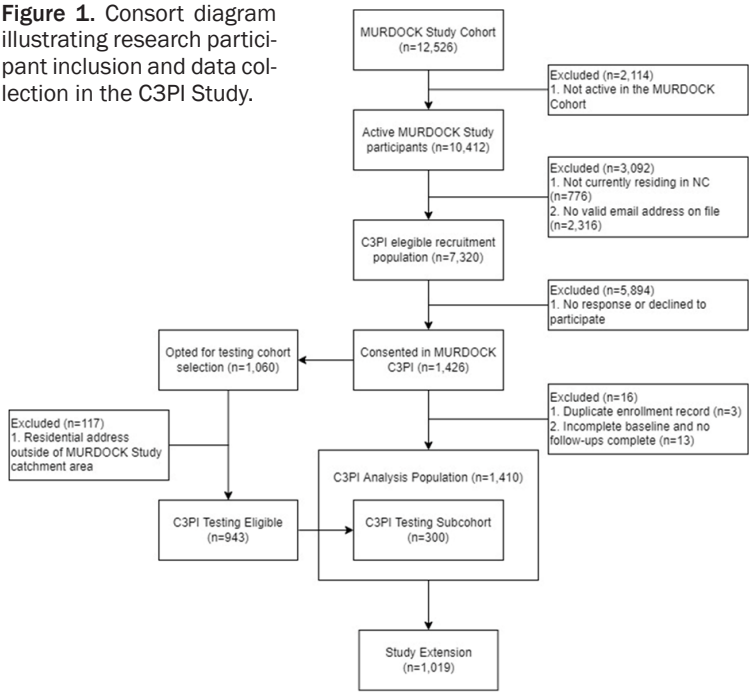

Figure 1. Consort diagram illustrating research participant inclusion and data collection in the C3PI Study.

consent, participants expressed their interest in testing sub-cohort participation.

Recruitment into the testing sub-cohort occurred after one month of recruitment into the survey cohort. A weighted, randomized selection schema approximated representation by sex, age, and race/ethnicity that reflected the Cabarrus County population distribution to support generation of population estimates of COVID-19 incidence and seroprevalence (antibody positivity). If a participant was selected for the testing sub-cohort but elected not to participate, the next individual with similar characteristics was invited to participate. This process continued until 300 sub-cohort participants were enrolled. Individuals who prematurely terminated participation in the testing sub-cohort were not replaced.

All recruitment materials, consent, questionnaires, return of results, and verbal study communications were available in English and Spanish to support population representativeness.

Ethics

The MURDOCK Study is approved by the Duke Health Institutional Review Board (IRB) (Approval Number: Pro00011196). Participants provided written informed consent, which included consent for re-contact for participation in future studies. The C3PI Study was approved by the Duke Health IRB (Approval Number: Pro00105703). Participants provided electronic informed consent within REDCap. The initial study period was from June 2020 through April 2021, with a study extension from May 2021 through December 2021. The study extension introduced remuneration to participants for completing bi-weekly surveys and monthly in-person blood draw visits and was approved by the Duke Health IRB as an amendment to the original protocol. A history of the actions of the Duke Health IRB on the C3PI Study protocol is provided as Supplementary Materials 1.

Data collection

Survey methods: All study participants completed a baseline questionnaire at study entry and follow-up surveys every two weeks. Surveys were administered and stored in REDCap and accessed by participants through a link sent via email. All data and metadata for the C3PI Study are stored in REDCap.

Questionnaires were developed in collaboration with investigators at UNC-CH and ECU to facilitate pooling data across studies. Questionnaires were modified as needed for the C3PI Study cohort and objectives while preserving the themes of the questionnaires created in collaboration with UNC-CH and ECU. A question bank for all questionnaires used in the C3PI Study is included in Supplementary Materials 2.

The baseline questionnaire assessed participant demographics and health, including medical illnesses and medications, symptoms of possible and/or prior COVID-19 illness, testing, and treatment; household features, lifestyle, and employment; perceived impact of the pandemic, perceptions about vaccination, and out-

look regarding the pandemic. Participants who did not complete the baseline questionnaire immediately after providing consent were contacted via email, telephone, and/or text to encourage completion.

Surveillance questionnaires were released to all participants at 2-week intervals on Monday of the survey week. Questionnaires addressed potential COVID-19 symptoms, illness and treatment, general health and wellbeing, perceptions about COVID-19 vaccination, and employment and risk to the participant and his/her household. As vaccines became available, questions about vaccination status were added to the survey. During survey weeks, reminders were sent via email and/or text to participants who had not yet completed the questionnaire. Participants were administratively removed from study participation and not replaced if they did not complete a survey for four consecutive 2-week survey cycles. All data collected before termination (self or administrative) remain available for analysis.

Testing sub-cohort methods

SARS-CoV-2 RT-PCR testing: Anterior nasal swab specimens for SARS-CoV-2 RT-PCR testing were collected at baseline and every two weeks, in conjunction with questionnaire administration. From July 21, 2020 to August 12, 2020, clinical study personnel observed all participants' baseline nasal swab collection to ensure correct specimen collection technique and use of kit materials. Participants who could not attend a supervised baseline collection visit were excluded from the testing sub-cohort and replaced according to the random selection schema. After the baseline visit, all nasal swab collection kits were sent to participants' home addresses for the remainder of the study. After collection, nasal swabs were placed into a cryovial containing PrimeStore® MTM and shipped the same day via UPS with a frozen cold pack for testing at the NC State Laboratory for Public Health (SLPH). RT-PCR testing used the TaqPath™ COVID-19 Combo Kit assay. Samples were excluded if they did not meet the laboratory's specimen acceptability criteria. Test results were reported as positive or negative for the SARS-CoV-2 virus.

SARS-CoV-2 antibody testing: Blood samples for serology testing were collected every other month (initial study period) or monthly (study extension period) by routine phlebotomy and processed onsite at the Duke CTSI research site in Kannapolis, NC. Blood collection was deferred for at least 28 days for participants with a positive RT-PCR test result to ensure staff safety. Blood was collected into a 3 mL red top tube, allowed to clot at room temperature for 45 minutes, then centrifuged at 3000 rpm for 15 minutes at 4°C to separate the serum. Serum was transferred to cryovials and stored onsite at -80°C until shipment in batches to the Immunology & Virology Quality Assessment Center within the Duke Human Vaccine Institute, Duke University, Durham, NC. Serology testing during the initial study period used the Abbott Alinity IgG nucleocapsid protein antibody assay. The test was considered positive if nucleocapsid IgG antibodies were detected at ≥1.40 index of the assay (https://www.fda.gov/media/137910/download). The assay has a specificity of 99.9% and a sensitivity of 100.0% for detecting IgG antibodies 17 days after the onset of symptoms [6]. During the 6-month study extension, in addition to the nucleocapsid IgG assay, serum samples were also tested for spike protein antibodies using the Abbott Alinity AdviseDx SARS-CoV-2 IgG II assay. The test was considered positive if IgG levels were ≥50.0 AU/mL (https://www.fda.gov/media/146372/download). The assay has an estimated specificity of 99.6% and sensitivity of 98.1% (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance).

Samples that tested positive for spike protein IgG were tested for neutralizing activity using the GenScript cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit. The assay has an estimated specificity and sensitivity of 100.0% (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance). Residual serum was frozen at -80°C and stored for future use in the Duke COVID-19 Biorepository (Pro00-105316).

Return of results

Aggregate questionnaire and testing results were shared with participants and the public

Table 1. Baseline demographics

	MURDOCK Overall (N= 10,412)	C3PI Study Eligible (N=7,320)	C3PI Study Cohort (N=1,410)	C3PI Testing Eligible (N=943)	C3PI Testing Sub-cohort (N=300)	Cabarrus County (2019) (N=216,453)*
Demographics						
Age	59 (48, 70)	59 (49, 70)	61 (51, 70)	61 (52, 70)	56 (47, 67)	37.9
Male	3383 (32.5)	2381 (32.5)	436 (30.9)	295 (31.3)	117 (39.0)	105,629 (48.8)
Race						
Black	1406 (13.7)	888 (12.1)	115 (8.2)	62 (6.6)	51 (17.0)	42,425 (19.6)
White	7482 (72.7)	5795 (79.9)	1,210 (86.6)	838 (89.5)	230 (76.7)	156,712 (72.4)
Asian	71 (0.7)	56 (0.8)	3 (0.2)	1 (0.1)	0 (0.0)	10,173 (4.7)
American Indian or Alaska Native	47 (0.5)	24 (0.3)	2 (0.1)	2 (0.2)	1 (0.3)	21,645 (0.1)
Native Hawaiian/Pacific Islander	7 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Ethnicity						
Hispanic	1414 (13.8)	527 (7.3)	72 (5.1)	40 (4.3)	33 (11.0)	24,026 (11.1)
Not Hispanic	8853 (86.2)	6695 (92.7)	1,328 (94.9)	901 (95.8)	266 (89.0)	192,427 (88.9)
Missing	145 (1.4)	98 (1.3)	10 (0.7)	2 (0.2)	1 (0.3)	–
Primary Language Spoken						
English			1,352 (97.5)	917 (98.2)	284 (95.3)	
Spanish			33 (2.4)	16 (1.7)	14 (4.7)	
Other			2 (0.1)	1 (0.1)	0 (0.0)	
Missing			23 (1.6)	9 (1.0)	2 (0.7)	

For categorical variables, values represent N (%) for non-missing values. For continuous variables, values represent the median (Q1, Q3) of non-missing values. *Data was retrieved from https://www.census.gov/newsroom/press-kits/2020/population-estimates-detailed.html.

throughout the study through various channels, including meetings with participants, email, social media, the lay press, and scientific publications. NCDHHS also received regular aggregate reports on accruing study data and *ad hoc* reports on areas of temporal focus. No individual participant identifying information was included in the reports. Testing sub-cohort participants received individual reports on their COVID-19 RT-PCR and SARS-CoV-2 serology results. These reports were also uploaded into REDCap.

The report template and accompanying interpretative information for returning serology results are shown in **Appendix 1**. Participants who tested positive by RT-PCR were contacted via phone by the study principal investigator. Attempts were made to contact the participant within 48 hours and continued until the participant was reached. During these calls, it was emphasized that results were research test results and that the participant should contact their primary physician for additional testing or treatment. They were provided general recommendations that followed the Centers for Disease Control and Prevention (CDC) guidance (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html) and were allowed to ask questions. Positive COVID-19 RT-PCR test results were available to the Cabarrus County Health Department to aid contact tracing efforts.

Statistical analyses

Descriptive data were generated using SAS (Statistical Analysis Software) Version 9.4, SAS Institute Inc, Cary, North Carolina, USA. No statistical testing was performed.

Results

Baseline characteristics

Demographics: **Table 1** shows baseline demographic characteristics of the C3PI Study cohort and testing sub-cohort compared with 2019 Cabarrus County census data, if available, and the eligible MURDOCK Study cohort. After applying weighting, the randomly selected testing sub-cohort was younger (56 vs 61 years), had more men (39.0% vs 30.9%) and a higher proportion of Hispanic and Black participants (Hispanic, 11.0% vs 5.1%, respectively and Black, 17.0% vs 8.2%, respectively) compared with the C3PI Study cohort. English was the pri-

Table 2. Anthropometric and clinical characteristics

	C3PI Study Cohort (N=1,410)	C3PI Testing Sub-Cohort (N=300)
Anthropometrics		
Height (inches)	66 (64, 69)	67 (64, 70)
Missing	26 (1.8)	5 (1.7)
Weight (lbs)	175 (149, 206)	180 (155, 210)
Missing	20 (1.4)	2 (0.7)
BMI	27.8 (24.4, 32.2)	27.8 (24.9, 31.6)
Missing	30 (2.1)	6 (2.0)
Medical History		
Allergies	707 (51.6)	159 (53.5)
Missing	39 (2.8)	3 (1.0)
Asthma	213 (16.0)	51 (17.5)
Missing	75 (5.3)	9 (3.0)
Diabetes	189 (14.3)	29 (10.0)
Missing	84 (6.0)	10 (3.3)
Hypertension	466 (34.4)	105 (35.5)
Missing	57 (4.0)	4 (1.3)
Cardiovascular Disease	116 (8.7)	25 (8.5)
Missing	82 (5.8)	6 (2.0)
Chronic Respiratory Disease	66 (5.0)	11 (3.8)
Missing	82 (5.8)	8 (2.7)
Chronic Kidney Disease	22 (1.7)	9 (3.1)
Missing	85 (6.0)	7 (2.3)
Chronic Liver Disease	15 (1.1)	4 (1.4)
Missing	90 (6.4)	9 (3.0)
Cancer	223 (16.7)	45 (15.4)
Missing	77 (5.5)	7 (2.3)
Weak Immune System	104 (7.9)	20 (6.9)
Missing	87 (6.2)	8 (2.7)
Other Chronic Condition	322 (24.5)	63 (21.8)
Missing	95 (6.7)	11 (3.7)
Lifestyle/Habits		
Smoking		
Current	50 (3.6)	9 (3.0)
Former	356 (25.7)	60 (20.1)
Never	979 (70.7)	229 (76.8)
Missing	25 (1.8)	2 (0.7)
E-cigarettes		
Current	9 (0.7)	1 (0.4)
Former	28 (2.1)	4 (1.4)
Never	1,304 (97.2)	279 (98.2)
Missing	69 (4.9)	16 (5.3)
Alcohol		
Current	611 (44.2)	140 (47.3)
Former	171 (12.4)	31 (10.5)

Never	600 (43.4)	125 (42.2)
Missing	28 (2.0)	4 (1.3)
Exercise		
Yes	1,010 (72.5)	215 (72.1)
Level of Exercise		
Easy	75 (7.5)	17 (8.1)
Medium (can hold a conversation)	630 (63.3)	119 (56.7)
Hard (but you can push yourself to continue)	251 (25.2)	59 (28.1)
Very Hard (cannot hold a conversation)	36 (3.6)	13 (6.2)
Extremely Hard (out of breath, your body wants to stop the exercise)	4 (0.4)	2 (1.0)
Days/week	4 (3, 5)	4 (3, 5)
No	384 (27.6)	83 (27.9)
Missing	16 (1.1)	2 (0.7)

For categorical variables, values represent N (%) for non-missing values. For continuous variables, values represent the median (Q1, Q3) of non-missing values. Missing represents N missing/N total for that column.

mary language spoken at home in the C3PI Study cohort and testing sub-cohort (97.5% and 95.3%, respectively).

The testing sub-cohort more closely approximated the racial and ethnic mix of Cabarrus County, NC, than the MURDOCK Study or C3PI Study cohort, but the sub-cohort was older (56.0 vs 37.9 years) and had a lower proportion of men (39.0% vs 48.8%) than the Cabarrus County population.

Anthropometric and clinical characteristics: In general, the C3PI Study cohort and testing sub-cohort had similar anthropometrics and medical histories (**Table 2**).

Within the C3PI Study cohort and testing sub-cohort (**Table 2**), 29.3% and 23.1%, respectively, were current or prior cigarette smokers, and 56.6% and 57.8%, respectively, reported current or prior alcohol use. Most participants in the C3PI Study cohort (72.5%) and the testing sub-cohort (72.1%) reported regular exercise, predominantly medium intensity (able to hold a conversation) in both groups (63.3% and 56.7%, respectively), with 25.2% and 28.1%, respectively, reporting hard intensity (having to push oneself to carry on a conversation).

Social determinants of health

Education: **Table 3** displays baseline social determinants of health. Overall, the study population was well educated; most participants had at least some college, a college degree, or an advanced degree. A greater proportion of the testing sub-cohort (36.1%) had graduated from a graduate school or higher degree program than the C3PI Study cohort (31.3%).

Household features and income: Most participants lived at their current residence for >10 years (65.2% C3PI Study cohort and 67.2% testing sub-cohort), and a median of 2 (2, 3) individuals lived within the household. The reported household income pre-pandemic was >$90,000 per year in 47.9% and 57.1% of the C3PI Study cohort and testing sub-cohort, respectively. Approximately 8% of individuals in both groups had incomes pre-pandemic <$30,000 per year. Most participants (57.5% and 55.4%, respectively) expected no change in income due to the pandemic, but just over one-third of participants (36.2% and 38.7%, respectively) anticipated a slight decrease.

Most participants in the C3PI Study cohort (96.6%) and testing sub-cohort (95.3%) reported having health insurance, most frequently private insurance purchased through employment or school. Reflecting differences in age and retired status, the proportion of participants having Medicare was higher in the C3PI Study cohort (36.9%) than the testing sub-cohort (25.4%).

Employment: Before the COVID-19 pandemic, 43.5% of the C3PI study cohort were employed full time, 36.7% were retired, and 1.7% were unemployed. Within the testing sub-cohort, 54.0% were employed full time and 27.3% were retired. Among those employed full or part-time pre-pandemic, 12.1% were healthcare workers, 9.9% other professionals, 8.4% educators, 4.4% essential service workers, and 1.6% first responders (**Table 3**).

Table 3. Baseline social determinants of health

	C3PI Study Cohort (N=1,410)	C3PI Testing Sub-Cohort (N=300)
Education		
Never attended school	1 (0.1)	0 (0.0)
Kindergarten-8th grade	3 (0.2)	0 (0.0)
Some high school	11 (0.8)	4 (1.3)
High school equivalency (GED)	18 (1.3)	2 (0.7)
High school graduate	67 (4.8)	13 (4.4)
Some college	304 (21.8)	50 (16.7)
College graduate	553 (39.7)	122 (40.8)
Graduate school or higher degree	435 (31.3)	108 (36.1)
Missing	18 (1.3)	1 (0.3)
Employment Pre-COVID		
Worked full time	613 (43.5)	162 (54.0)
Worked part time	178 (12.6)	42 (14.0)
Unemployed	24 (1.7)	3 (1.0)
Furlough/temporarily laid off	5 (0.4)	1 (0.3)
Looking for work	15 (1.1)	2 (0.7)
Retired	518 (36.7)	82 (27.3)
Homemaker	96 (6.8)	17 (5.7)
Student	7 (0.5)	1 (0.3)
On mat/pat leave	2 (0.1)	0 (0.0)
On disability	58 (4.1)	12 (4.0)
Other	26 (1.8)	3 (1.0)
Type of work (FT/PT work)		
Healthcare professional	171 (12.1)	42 (14.0)
Other professional	139 (9.9)	47 (15.7)
Essential service worker	62 (4.4)	14 (4.7)
Other service worker	26 (1.8)	8 (2.7)
First responder	22 (1.6)	7 (2.3)
Managerial	88 (6.2)	25 (8.3)
Administrative support	96 (6.8)	18 (6.0)
Educator	118 (8.4)	26 (8.7)
Farming etc	6 (0.4)	4 (1.3)
Precision prod/craft/rep	7 (0.5)	1 (0.3)
Operators/fabricator/labor	11 (0.8)	5 (1.7)
Military	1 (0.1)	0 (0.0)
Household Features		
How long at current address		
0-3 years	222 (16.1)	43 (14.5)
4-6 years	157 (11.4)	33 (11.1)
7-10 years	102 (7.4)	21 (7.1)
10+ years	901 (65.2)	199 (67.2)
Missing	28 (2.0)	4 (1.3)
How many live there	2 (2, 3)	2 (2, 4)
Missing	23 (1.6)	1 (0.3)
How many below 18	0 (0, 0)	0 (0, 1)
Missing	40 (2.8)	8 (2.7)
Household income		
Less than $10,000	16 (1.2)	2 (0.7)

$10,000-$19,999	26 (2.0)	6 (2.1)
$20,000-$29,999	71 (5.3)	13 (4.6)
$30,000-$49,999	175 (13.2)	24 (8.5)
$50,000-$74,999	237 (17.8)	44 (15.6)
$75,000-$89,999	168 (12.6)	32 (11.3)
$90,000 or more	636 (47.9)	161 (57.1)
Missing	81 (5.7)	18 (6.0)
Expected Income change due to COVID		
Decrease significantly	152 (11.1)	41 (13.9)
Decrease slightly	358 (26.2)	75 (25.5)
Stay the same	785 (57.5)	163 (55.4)
Increase slightly	65 (4.8)	12 (4.1)
Increase significantly	6 (0.4)	3 (1.0)
Missing	44 (3.1)	6 (2.0)
Healthcare insurance		
Yes	1,344 (96.6)	284 (95.3)
No	47 (3.4)	14 (4.7)
Missing	19 (1.3)	2 (0.7)
Healthcare insurance types		
Insurance purchased directly through a health plan or insurance company	57 (4.3)	12 (4.2)
Insurance purchased through a state or federal health insurance exchange such as healthcare.gov	53 (4.0)	12 (4.2)
Medi-Gap	4 (0.3)	3 (1.1)
Medicaid	13 (1.0)	2 (0.7)
Medicare	493 (36.9)	72 (25.4)
Military health care (TRICARE/VA/CHAMP-VA)	29 (2.2)	5 (1.8)
Private health insurance through a job or School	660 (49.3)	169 (59.5)
Other, please specify	29 (2.2)	9 (3.2)
Missing	72 (5.1)	16 (5.3)

For categorical variables, values represent N (%) for non-missing values. For continuous variables, values represent median (Q1, Q3) of non-missing values. Missing represents N missing/N total for that column.

Of 1,340 participants reporting employment status for both pre-pandemic and at C3PI Study enrollment, 153 (11.4%) reported a change in employment (**Table 4**). Of 576 employed neither full- nor part-time pre-pandemic, 7 (1.2%) were employed part-time at the baseline survey early in the pandemic. Of 161 individuals employed part-time pre-pandemic, 1 (0.6%) was employed full-time at baseline, and 44 (27.3%) were employed neither full- nor part-time at baseline. Of 603 individuals employed full-time pre-pandemic, 30 (5.0%) were employed part-time at the baseline survey, and 71 (11.8%) were employed neither full- nor part-time. Patterns were similar in the testing sub-cohort.

Among 673 C3PI Study participants who reported either full- or part-time employment at baseline, 287 (44.6%) reported a change in work-from-home status from pre-pandemic to the baseline C3PI Study survey (**Table 5**). Among 152 individuals who never or hardly ever worked at home pre-pandemic, 50 (32.9%) sometimes or often/always worked from home at the baseline survey. Among 491 participants working sometimes or often/always from home pre-pandemic, 168 (34.2%) never/hardly ever worked from home at baseline. Patterns were similar in the testing sub-cohort.

Baseline health status

General health at baseline: At baseline, most participants reported their general health within the last two weeks as either very good or good (72.7%); 7.3% reported their health as fair or poor (**Table 6**). A minority (11.8%) of participants reported that stress played a very significant role in their lives. At baseline, 71.0% of participants reported having none of the potential symptoms of COVID-19 prior to enrollment. Rating how well informed they were about the pandemic on a scale from 0-10 (10

Table 4. Change in employment status from pre-pandemic to baseline survey

	C3PI Study Cohort (N=1,340)*			C3PI Testing Sub-Cohort (N=291)*		
	Employed FT at Baseline	Employed PT at Baseline	Neither FT or PT at Baseline	Employed FT at Baseline	Employed PT at Baseline	Neither FT or PT at Baseline
Employed FT pre-COVID	502	30	71	135	10	18
Employed PT pre-COVID	1	116	44	1	29	10
Neither FT nor PT pre-COVID	0	7	569	0	1	87

*Participants who did not respond to both pre-pandemic and baseline employment status survey questions were excluded.

Table 5. Work from home change between pre-COVID and baseline periods among those employed at baseline

	C3PI Study Cohort (N=643)*			C3PI Testing Sub-Cohort (N=173)*		
	Never/hardly ever	Sometimes	Often/always	Never/hardly ever	Sometimes	Often/always
Never/hardly ever pre-COVID	94	8	50	28	2	16
Sometimes pre-COVID	24	15	7	5	2	3
Often/always pre-COVID	144	54	247	37	13	67

*Participants who did not respond to both pre-pandemic and the baseline employment status survey questions or were not employed at both timepoint were excluded.

most informed), the median was 9 (8, 10) on a scale of 0 to 10 (10 most informed).

COVID-19 mitigation strategies and behaviors: At baseline, most participants stayed home if they felt sick (92.4%), but there was wide variation in other recommended mitigation strategies (**Table 4**). Over half (55.5%) of participants always used facemasks in public/at work, 73.8% always avoided large crowds and gatherings, and 74.8% washed/sanitized their hands frequently, but always maintaining 6 feet of social distancing was practiced by only 44.7%.

Approximately half of participants (51.2%) reported working or studying from home instead of going into an office/class, but only 8.6% reported that household members consistently stayed home, aside from getting groceries. Most participants reported following government guidelines, rules, or shelter-in-place orders (88.4%), 73.4% canceled personal travel, and 82.6% postponed planned social or personal activities. Approximately 40% of participants stockpiled food or water (38.2%), and 53.6% canceled doctor appointments due to the COVID-19 pandemic.

Discussion

The C3PI Study is a prospective, longitudinal cohort study to complement and inform the ongoing initiatives of NCDHHS to stop the spread of COVID-19. It is part of a collaborative effort among UNC-CH, ECU, and Duke University supported by NCDHHS through internal funds and grants from the CDC. The C3PI Study used an existing longitudinal cohort, the MURDOCK Study Community Registry, to recruit participants to investigate the prevalence, tempo, and responses to the COVID-19 pandemic within Cabarrus County, NC.

This study will shed light on community prevalence of active COVID-19 infection and SARS-CoV-2 antibodies as mitigation efforts are modified, and vaccines are deployed. Previous studies of COVID-19 in NC explored the effects of the pandemic on telemedicine, burn center admission, and mental health [7-9], the spread of COVID-19 in university settings, asymptomatic community spread, knowledge, and practice of COVID-19 prevention measures within specific communities, and surveillance systems [10-15]. Further, Lopez, *et al.* tested remnant inpatient and outpatient plasma and serum samples from four hospital-based clinical laboratories within the UNC Healthcare System to describe the seroprevalence of healthcare-seeking individuals in central NC [16]. A longitudinal cohort study investigating SARS-CoV-2 infection and the pandemic's effects on mental health in healthcare workers, ancillary support staff, and their families is also

Table 6. Baseline health and COVID-19 response and behaviors

	C3PI Study Cohort (N=1,410)	C3PI Testing Sub-Cohort (N=300)
General Health Assessments		
General health last 2 weeks		
Excellent	274 (20.0)	54 (18.2)
Very good	619 (45.2)	137 (46.1)
Good	376 (27.5)	90 (30.3)
Fair	90 (6.6)	14 (4.7)
Poor	10 (0.7)	2 (0.7)
Missing	41 (2.9)	3 (1.0)
Pandemic stress		
Very significant	161 (11.8)	38 (12.8)
Somewhat significant	695 (50.9)	151 (50.8)
Not very significant	411 (30.1)	92 (31.0)
Not at all significant	98 (7.2)	16 (5.4)
Missing	45 (3.2)	3 (1.0)
COVID Assessments		
How well informed (1-10)	9 (8, 10)	9 (8, 10)
Missing	89 (6.3)	13 (4.3)
COVID symptoms prior to enrollment		
Yes	393 (29.0)	89 (30.4)
No	962 (71.0)	204 (69.6)
Missing	55 (3.9)	7 (2.3)
COVID Mitigation Behaviors		
Household members stay home		
Always	118 (8.6)	26 (8.9)
Most of the time	920 (67.1)	194 (66.4)
Half of the time	184 (13.4)	36 (12.3)
Less than half of the time	99 (7.2)	22 (7.5)
Never	50 (3.7)	14 (4.8)
Missing	39 (2.8)	8 (2.7)
Face mask in public/at work		
Always	765 (55.5)	167 (56.4)
Most of the time	394 (28.6)	76 (25.7)
Half of the time	80 (5.8)	22 (7.4)
Less than half of the time	99 (7.2)	25 (8.5)
Never	41 (3.0)	6 (2.0)
Missing	31 (2.2)	4 (1.3)
Wash hands/sanitizer frequently		
Always	1,031 (74.8)	222 (74.7)
Most of the time	300 (21.8)	64 (21.5)
Half of the time	36 (2.6)	10 (3.4)
Less than half of the time	10 (0.7)	1 (0.3)
Never	2 (0.2)	0 (0.0)
Missing	31 (2.2)	3 (1.0)
Stay 6 feet away from others		
Always	615 (44.7)	120 (40.4)
Most of the time	696 (50.6)	161 (54.2)

Half of the time	48 (3.5)	13 (4.4)
Less than half of the time	11 (0.8)	3 (1.0)
Never	5 (0.4)	0 (0.0)
Missing	35 (2.5)	3 (1.0)
Avoid large gatherings and crowds		
Always	1,015 (73.8)	211 (71.3)
Most of the time	310 (22.6)	74 (25.0)
Half of the time	21 (1.5)	6 (2.0)
Less than half of the time	21 (1.5)	3 (1.0)
Never	8 (0.6)	2 (0.7)
Missing	35 (2.5)	4 (1.3)
Avoided high risk people		
Always	985 (71.6)	207 (69.7)
Most of the time	326 (23.7)	75 (25.3)
Half of the time	32 (2.3)	8 (2.7)
Less than half of the time	15 (1.1)	3 (1.0)
Never	18 (1.3)	4 (1.4)
Missing	34 (2.4)	3 (1.0)
Avoided food restaurants/takeout		
Always	171 (12.5)	30 (10.1)
Most of the time	531 (38.8)	96 (32.3)
Half of the time	273 (19.9)	66 (22.2)
Less than half of the time	209 (15.3)	54 (18.2)
Never	185 (13.5)	51 (17.2)
Missing	41 (2.9)	3 (1.0)
Work/study at home		
Always	661 (51.2)	140 (49.6)
Most of the time	177 (13.7)	42 (14.9)
Half of the time	66 (5.1)	19 (6.7)
Less than half of the time	66 (5.1)	21 (7.5)
Never	320 (24.8)	60 (21.3)
Missing	120 (8.5)	18 (6.0)
Avoid shaking hands/touching		
Always	991 (72.0)	211 (71.0)
Most of the time	308 (22.4)	73 (24.6)
Half of the time	43 (3.1)	8 (2.7)
Less than half of the time	20 (1.5)	5 (1.7)
Never	14 (1.0)	0 (0.0)
Missing	34 (2.4)	3 (1.0)
Stayed home if I was sick		
Always	1,223 (92.4)	260 (91.5)
Most of the time	55 (4.2)	15 (5.3)
Half of the time	7 (0.5)	1 (0.4)
Less than half of the time	7 (0.5)	4 (1.4)
Never	31 (2.3)	4 (1.4)
Missing	87 (6.2)	16 (5.3)
Wiped surfaces with disinfectant		
Always	653 (47.7)	133 (45.1)
Most of the time	459 (33.6)	109 (36.9)

Half of the time	153 (11.2)	29 (9.8)
Less than half of the time	83 (6.1)	20 (6.8)
Never	20 (1.5)	4 (1.4)
Missing	42 (3.0)	5 (1.7)
COVID life responses		
Canceled or postponed planned travel for Work	340 (24.1)	93 (31.0)
Canceled or postponed travel for Pleasure	1,035 (73.4)	220 (73.3)
Canceled or postponed personal or social Activities	1,164 (82.6)	261 (87.0)
Cancelled a doctor's appointment	756 (53.6)	151 (50.3)
Stockpiled food or water	539 (38.2)	116 (38.7)
Followed government guidelines or rules to shelter in place	1,246 (88.4)	275 (91.7)

For categorical variables, values represent N (%) for non-missing values. For continuous variables, values represent median (Q1, Q3) of non-missing values. Missing represents N missing/N total for that column.

currently ongoing [17]. However, none of these studies address longitudinally the community COVID-19 incidence and SARS-CoV-2 seroprevalence together while also exploring community and individual perceptions and effects of the pandemic with the richness and granularity afforded by frequent survey and sample collection time points. In conducting the C3PI Study, we aim to address these gaps and provide a comprehensive community-level picture of the COVID-19 pandemic in Cabarrus County, NC that can complement other efforts across NC.

Insights from the C3PI study baseline survey

Only 3-4 months into the pandemic, we launched the C3PI Study and we already observed effects of the pandemic within our cohort and were able to assess responses to recommended mitigation strategies.

General and health-related observations: Overall, the cohort felt well informed about the pandemic. However, stress related to the pandemic was substantial with 50.9% rating their pandemic stress somewhat significant and 11.8% rating it as significant. Only 5 participants reported having tested positive for COVID-19 prior to enrollment, and most rated their baseline health as good, very good, or excellent. We also established baselines for lifestyle behaviors (e.g., exercise, alcohol use, smoking) that we will be able to track over time during the pandemic.

Early observations on the societal effect of the pandemic: The pandemic effects on employment were already evident. Over a quarter of people employed part-time at the onset of the pandemic were no longer employed at enrollment. Nearly 11.8% of those working full-time at the start of the pandemic were no longer employed at baseline and 5.0% had become part-time employed. About one-third of full or part-time employees who had never/hardly ever worked from home pre-pandemic were working from home at the start of the pandemic.

Nearly three-quarters of participants reported they had cancelled personal travel and 82.6% had postponed other social or personal activities. We also observed "hoarding behavior" in our cohort that mirrored the experience nationally. Additionally, the pandemic onset was associated with a high rate of cancellation of healthcare appointments (53.6%) that if sustained may have long-lasting effects on health well after the pandemic eases [18-20].

Mitigation practices: At the time we started enrollment in June of 2020, relatively early in the pandemic, the benefit of wearing face masks was established and recommendations for other mitigation strategies were well disseminated, but there was resistance among many [21]. We found that, at this point, nearly 46.8% of participants were not always wearing face masks in public or at work, and only 44.7% were always practicing 6 feet of social distancing. However, approximately three-quarters of participants reported avoiding large crowds and gatherings and frequently washing/sanitizing hands.

These observations and others have established a baseline from which to explore trajectories over time as the pandemic ebbs and flows

and to examine the factors that influence the trajectories as well as their relationships with infection and immunity over time.

Strengths and limitations

A major strength of the C3PI Study is using a longstanding, established cohort (MURDOCK Study) to recruit participants. Using an established cohort with an existing relationship accelerated recruitment (all participants identified and enrolled, and data collection begun within six weeks of IRB approval) and supports a higher retention rate than community samples recruited *de novo*. To augment this established relationship, we used multiple engagement efforts, including informational Zoom sessions for participants with the study PIs, study team, and subject matter experts on the COVID-19 pandemic, as well as updates in multiple media outlets and social media posts on designated platforms. C3PI Study participants received monthly newsletters that included study updates, community news, and raffle prize winners (1 winner per survey time point). Individual testing results (testing sub-cohort) and aggregate survey results are shared frequently with participants throughout the study. Notably, the richness and granularity of longitudinal testing and survey data collected in the C3PI Study and across the research network are unparalleled, creating a unique dataset and cohort that can be leveraged for future studies.

The C3PI Study has potential limitations. While the use of the MURDOCK Study cohort from which to recruit the C3PI Study participants accelerated recruitment, maximizing duration of follow up, and enhanced engagement and serial survey completion, the population had several important demographic differences from the Cabarrus County population (older, more women and White participants, higher education and income levels, and highly insured) that may limit generalizability. However, the sample size is substantial and will allow insights into pandemic behaviors and consequences over time as the pandemic evolves. Further, the weighted random subset more closely approximates the county demographics and should allow generalization of infection and immune response results to the broader population. Survey aspects of the study are self-reported, which could lead to response or recall bias on some elements. We believe that using a purely digital platform and having short intervals (2 weeks) between follow-up surveys will mitigate this. At-home collection of nasal swabs by participants protects study staff from inadvertent exposure to COVID-19 and conserves personal protective equipment (PPE), and is convenient for participants. However, it could introduce errors in specimen collection, processing, and/or shipping that could result in missed COVID-19 RT-PCR testing events or errant results. However, a previous study found at-home self-collection of saliva and combined nasal-oropharyngeal swabs was feasible and adequate for detecting SARS-CoV-2 [22]. We attempted to mitigate possible errors by directly observing participants' first nasal swab collection to ensure a firm understanding of correct procedural technique and at-home kit instructions. Additionally, we had assistance readily available and monitored the adequacy of sample collection, with reinstruction and coaching using written instructions, videos, and one-on-one coaching as needed.

What can we learn from the C3PI study?

In addition to real-time monitoring of the pandemic to support NCDHHS surveillance efforts, future analyses of the C3PI Study database will assess relationships among demographic and socioeconomic factors and comorbid conditions with confirmed symptomatic and asymptomatic COVID-19 infections, population immunity and outcomes, use of mitigation strategies, rates of vaccination and vaccination hesitancy, and the overall effects of the pandemic on the community. Geospatial analysis may be performed to identify disease transmission hotspots for potential use in future public health responses. We also expect to harmonize and pool data collected across all NCDHHS collaborative studies and potentially other studies conducted in NC. An enhanced understanding of the community prevalence and perceptions of the COVID-19 pandemic from this longitudinal study will inform policymakers and community members in NC, and more broadly, on progress toward controlling the pandemic and providing insights into future public health efforts.

Conclusion

We describe the design, methods, and baseline characteristics of the C3PI Study, a prospective cohort that will contribute valuable information about community incidence of COVID-19 and SARS-CoV-2 seroprevalence as the response to the COVID-19 pandemic evolves. Data from the completed C3PI Study cohort will provide a substantial resource that will have implications and applications far beyond its local context.

Acknowledgements

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Disclosure of conflict of interest

None.

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Appendix 1

Duke Human Vaccine Institute

IVQAC

Immunology & Virology Quality Assessment Center

SARS-CoV-2 IgG Results Summary Report

Methodology: Abbott Alinity i-series SARS-CoV-2 IgG Assay
Study: C3PI
Patient ID: XXXXXXXX
Requested by: Dr. Kristin Newby, M.D.
Report Date: DD/MMM/YYYY

Results:

PID	Timepoint	Calibrator/Sample Ratio	Result
XXXXXXXX	Month 1	X.XXXX	Negative
	Month 3	X.XXXX	Borderline/Negative
	Month 5	X.XXXX	Positive

Comments: N/A

Technician Signature: _____ Date: _____

Verified by: _____ Date: _____

Supervisor Signature: _____ Date: _____

**These studies are for research purposes only. Not for clinical purposes. **

Duke Human Vaccine Institute – IVQAC Lab
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Duke Clinical & Translational Science Institute

Translational Population Health Research

MURDOCK STUDY

Managed by Duke Clinical & Translational Science Institute

[Date]

Dear **[Participant name]**,

Thank you for participating in the MURDOCK Cabarrus County COVID-19 Prevalence & Immunity (C3PI) Study! The attached lab report contains your antibody testing result. Please read the information below carefully to understand what your result means. If you have further questions, please contact us at 704-250-5861 or transpop@duke.edu.

What is COVID-19 antibody testing?

When you recover from an infection like COVID-19, your immune system makes antibodies to recognize and fight the same infection in the future. These antibodies remain in your blood. You can have a blood test to determine whether your body has built up antibodies against that infection. Antibodies usually form 1 to 3 weeks after an infection starts. If your infection is active, your blood may not contain enough antibodies yet to be detected. Antibody tests cannot tell you whether you currently have the virus.

What do my antibody test results mean?

- A positive antibody test means that you have antibodies to COVID-19 in your blood.
- You may test positive because you had a COVID-19 infection without symptoms or without feeling badly. This is called an asymptomatic infection.
- It is possible to test positive for antibodies even if you never had the infection. This is called a false positive.
- If you test positive for antibodies, it is unclear whether the antibodies will protect you from a future COVID-19 infection. In other words, you may not have COVID-19 immunity.
- It is possible to have a COVID-19 infection but to test negative for antibodies. This is called a false negative. False negatives may occur if you had a mild infection and your body did not build a big immune response, or if you got the test too early to have built antibodies.
- The rates of false positives and false negatives for antibody tests are unknown.
- If you test negative for COVID-19 antibodies, it suggests that you have not been infected with COVID-19. You may still get sick, or you may have recently been exposed to the virus. It takes 1 to 3 weeks for antibodies to show up in your blood. You could still spread the virus.

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Duke Clinical & Translational Science Institute

Translational Population Health Research

MURDOCK STUDY

Managed by Duke Clinical & Translational Science Institute

- A borderline result indicates that the test could not determine whether you have antibodies or not.

Do antibody tests safely measure my body's level of protection from COVID-19?

There is not enough evidence yet to know if a person is 100% protected from a COVID-19 infection because they have tested positive for antibodies. The test may help determine how many people had COVID-19 infections. It may also aid in research to make a vaccine.

If I have a positive antibody test, do I still need to wear a mask?

Regardless of test results, everyone must wear a facemask to help prevent the spread of COVID-19 infection.

For more information, please visit the Centers for Disease Control at CDC.gov or the World Health Organization at WHO.int

We appreciate your participation in our study, and your help in learning more about COVID-19 infection in our community.

Sincerely,

The MURDOCK C3PI Study Team

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Completed Submissions

Protocol Status:	Approved
Principal Investigator:	**Newby, L Kristin**
Protocol Title:	MURDOCK Cabarrus County COVID-19 Prevalence and Immunity (C3PI) Study

Reference Number	Request Type	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
Pro00105703-SE-5.0	DUHS IRB SAE/AE form						
	DUHS IRB SAE/AE form	Duke Health IRB		Expedite		Complete - No Further Action Required	03/29/2022 11:16:23 AM EDT
Pro00105703-KSP-18.0	DUHS IRB KSP Change Form						
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively		Approved	03/22/2022 01:49:55 PM EDT
Pro00105703-KSP-17.0	DUHS IRB KSP Change Form						
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Pro00105703-AMD-19.0	DUHS IRB Amendment Form						
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Pro00105703-KSP-16.0	DUHS IRB KSP Change Form						
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	DUHS IRB KSP Change Form	Duke Health IRB		Returned for Corrections			09/14/2021 01:06:08 PM EDT
Pro00105703-AMD-18.0	DUHS IRB Amendment Form						
	DUHS IRB Amendment Form	Duke Health IRB		Expedite		Approved	08/20/2021 10:33:04 AM EDT
Pro00105703-KSP-15.0	DUHS IRB KSP Change Form						
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively		Approved	08/11/2021 05:19:59 PM EDT
Pro00105703-AMD-17.0	DUHS IRB Amendment Form						

	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	07/31/2021 12:17:08 PM EDT
Pro00105703-KSP-14.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	07/28/2021 03:10:35 PM EDT
Pro00105703-KSP-13.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	07/08/2021 03:27:58 PM EDT
Pro00105703-AMD-16.0	DUHS IRB Amendment Form					
	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	06/30/2021 02:01:29 PM EDT
Pro00105703-AMD-15.0	DUHS IRB Amendment Form					
	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	06/17/2021 02:03:34 PM EDT
Pro00105703-KSP-12.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	06/14/2021 09:31:11 AM EDT
Pro00105703-AMD-14.0	DUHS IRB Amendment Form					
	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	06/08/2021 05:02:30 PM EDT
Pro00105703-AMD-13.0	DUHS IRB Amendment Form					
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Pro00105703-AMD-12.0	DUHS IRB Amendment Form					
	Submission Correction for DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	05/12/2021 07:57:17 AM EDT
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Pro00105703-AMD-11.0	DUHS IRB Amendment Form					
	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	04/27/2021 03:20:55 PM EDT

Pro00105703-AMD-10.0	DUHS IRB Amendment Form					
	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	04/21/2021 01:51:57 PM EDT
Pro00105703-SE-4.0	DUHS IRB SAE/AE form					
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Pro00105703-AMD-9.0	DUHS IRB Amendment Form					
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Pro00105703-KSP-11.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	03/01/2021 04:35:59 PM EST
Pro00105703-KSP-10.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	02/01/2021 02:27:31 PM EST
Pro00105703-KSP-9.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	01/27/2021 08:45:21 AM EST
Pro00105703-KSP-8.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	01/07/2021 04:06:41 PM EST
Pro00105703-SE-3.0	DUHS IRB SAE/AE form					
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Pro00105703-AMD-8.1	DUHS IRB Amendment Form					
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Pro00105703-SE-2.0	DUHS IRB SAE/AE form					
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Pro00105703-AMD-7.0	DUHS IRB Amendment Form					
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	DUHS IRB Amendment Form	Duke Health IRB		Returned for Corrections		09/18/2020 09:42:22 PM EDT
Pro00105703-AMD-6.0	DUHS IRB Amendment Form					
	Submission Correction for DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	09/04/2020 01:49:30 PM EDT
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Pro00105703-KSP-6.0	DUHS IRB KSP					
Pro00105703-KSP-2.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	06/08/2020 03:26:13 PM EDT
Pro00105703-AMD-2.0	DUHS IRB Amendment Form					
	DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	06/08/2020 05:08:51 PM EDT
Pro00105703-KSP-1.0	DUHS IRB KSP Change Form					
	DUHS IRB KSP Change Form	Duke Health IRB		Process Administratively	Approved	06/03/2020 12:10:14 PM EDT
Pro00105703-AMD-1.0	DUHS IRB Amendment Form					
	Submission Correction for DUHS IRB Amendment Form	Duke Health IRB		Expedite	Approved	06/04/2020 02:00:29 PM EDT
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Pro00105703-INIT-1.0	Initial Review Submission Packet					

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	Submission Correction for DUHS IRB Amendment Form	Duke Health IRB		Expedite	Modifications Required	07/02/2020 05:07:44 PM EDT
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Pro00105703-AMD-3.0	DUHS IRB Amendment Form					
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Supplementary Materials 1. Ethical approval report.

Supplementary Materials 2. C3PI study questionnaire

Enrollment Questions

Personal & Household Information

Please review and confirm the following information from your MURDOCK Study record.

1. First name [free text]

2. Last name [free text]

3. Date of birth [free text, validation: mm/dd/yyyy]

4. Sex

   a. Female [BRANCH 111]
   b. Male

5. Race [checkbox-check all that apply]

   a. White/Caucasian
   b. Black or African American
   c. American Indian or Alaska Native
   d. Asian
   e. Native Hawaiian or other Pacific Islander
   f. Other race
   g. Don't know/not sure/prefer not to answer

6. Ethnicity

   a. Hispanic or Latino
   b. Not Hispanic or Latino
   c. Don't know/not sure/prefer not to answer

7. Current email address

8. Current residential address

   a. Street address [free text]
   b. City [free text]
   c. State [free text]
   d. Zip Code [free text]

Please answer the following questions about your household. For this study, household is defined as a residence, and its occupants, regarded as a unit.

9. How long have you lived at your current residential address? [radio button]

   a. 0-3 years
   b. 4-6 years
   c. 7-10 years
   d. 10+ years

10. How many total people (including yourself) live in this household? [dropdown: 1-12, 12+]

11. How many of the people in your household are below the age of 18? [dropdown: 0-11]

[The following question will branch if answer to people below 18 is >0]

12. If the COVID-19 pandemic caused your household to adjust to changes in child care, or having to home school, how difficult has that been? [radio button]

   a. Not difficult
   b. Somewhat difficult
   c. Very difficult
   d. Extremely difficult
   e. Not applicable, no changes

13. What is the primary language spoken in your household? [radio button]

   a. English
   b. Spanish
   c. Other, please specify [free text]

14. How many dogs live in this household? [free text, validation: integer, 0 for no dogs]

15. How many cats live this household? [free text, validation: integer, 0 for no cats]

16. What was your approximate total household income last year from all sources, before taxes?

   a. less than $10,000
   b. $10,000-$19,999
   c. $20,000-$29,999
   d. $30,000-$49,999
   e. $50,000-$74,999

f. $75,000-$89,999

g. $90,000 or more

17. Before the COVID-19 pandemic, did you have regular caregiving responsibilities for someone who didn't live in your household (ex. elderly parent or sibling who you regularly visited and supported, etc.)? [yes/no]

a. Yes [BRANCH]

b. No

18. If yes, how difficult has it been to continue providing this care due to the COVID-19 pandemic?

a. not difficult

b. somewhat difficult

c. very difficult

d. extremely difficult

Please answer the following questions about you.

19. What kind of mobile phone do you have? [radio button]

a. iOS (Apple iPhone)

b. Android (Google, Samsung)

c. Other, please specify [free text]

d. Do not have a mobile phone

20. Do you own any of the following wearable devices? [checkbox]

a. Fitbit

b. Apple Watch

c. Garmin

d. Samsung

e. Other, please specify [free text]

f. Do not own any of these devices

21. What is your height?

a. Feet [free text, validation: integer]

b. Inches [free text, validation: integer]

22. What is your weight?

a. Pounds [free text, validation: integer]

23. What is the highest level of education or schooling you have completed?

a. never attended school

b. kindergarten-8th grade

c. some high school

d. high school equivalency (GED)

e. high school graduate

f. some college

g. college graduate

h. graduate school, or higher degree, graduate

24. Are you covered by any type of medical or health insurance (including private insurance, insurance you purchased, Medicare, Medicaid, or any other health insurance program)? [radio button]

a. Yes [BRANCH]

b. No

c. Don't know

25. What is the primary health insurance coverage that you have? [radio button]

a. Private health insurance through a job or school

b. Insurance purchased through a state or federal health insurance exchange such as healthcare.gov

c. Insurance purchased directly through a health plan or insurance company

d. Medicare

e. Medi-Gap

f. Medicaid

g. Military health care (TRICARE/VA/CHAMP-VA)

h. Indian Health Service

i. Other, please specify [free text]

26. Have you ever served on active duty in the U.S. Armed Forces? *Active duty includes serving in the U.S. Armed Forces as well as activation from the Reserves or National Guard.*

a. Yes, on active duty in the past, but not now [BRANCH]

b. Yes, now on active duty [BRANCH]

c. No, never on active duty except for initial/basic training

d. No, never served in the U.S. Armed Forces

27. In which branch of the service did/do you serve? *(Mark any that apply)* [checkbox]

a. Army

b. Navy

c. Air Force

d. Marine Corps

e. Coast Guard

f. National Guard

g. Merchant Marines

h. National Oceanic and Atmospheric Administration (NOAA)

i. Public Health Service

j. None

28. What time period(s) did you serve? *(Mark any that apply)*

a. September 2001 or later

b. August 1990 to August 2001

c. May 1975 to July 1990

d. August 1964 to April 1975 (Vietnam era)

e. February 1955 to July 1964

f. July 1950 to January 1955 (Korean War)

g. January 1947 to June 1950

h. December 1941 to December 1946 (WWII)

i. November 1941 or earlier

29. Have you ever been enrolled in VA health care?

a. Yes

b. No

c. Don't know

30. Have you ever used any VA health care benefits?

a. Yes [BRANCH]

b. No

c. Don't know

31. Do you currently use the VA for your health care?

a. Yes [BRANCH]

b. No

c. Don't know

32. Which VA location(s)?

a. Salisbury

b. Durham

c. Fayetteville

d. Asheville

e. Other, please specify [free text]

33. Have you ever been given a diagnosis of any of the following? [matrix]

a. Allergies [Yes, No, Don't Know]

b. Asthma [Yes, No, Don't Know]

c. Diabetes [Yes, No, Don't Know]

d. Hypertension [Yes, No, Don't Know]

e. Cardiovascular disease such as heart attack, heart failure, angina, etc. [Yes, No, Don't Know]

f. Chronic respiratory disease such as chronic obstructive pulmonary disease (COPD), emphysema, chronic bronchitis, etc. [Yes, No, Don't Know]

i. If yes, do you *currently* use home oxygen (O_2)? [Yes, No, Don't know]

- If yes, how much, on average: [dropdown 1-10 L/min]

g. Chronic kidney disease [Yes, No, Don't Know]

i. If yes, are you *currently* on dialysis?

h. Chronic liver disease, such as cirrhosis, etc. [Yes, No, Don't Know]

i. Cancer [Yes, No, Don't Know]

i. If yes, are you *currently* receiving chemotherapy

j. Weakened immune system, such as HIV, chronic corticosteroid treatment, organ transplant recipient, or on another medication that weakens the immune system [Yes, No, Don't Know]

k. Other chronic condition, please specify [free text]

Lifestyle

Please answer the following questions about yourself, including exercise habits, smoking history and alcohol use.

34. In general, how would you have rated your health before the COVID-19 pandemic? [radio button]

a. Excellent

b. Very good

c. Good

d. Fair

e. Poor

35. At least once a week, do you engage in regular activity like brisk walking, jogging, bicycling, swimming, etc. long enough to work up a sweat, get your heart pumping, or get out of breath? [yes/no]

a. Yes [BRANCH 36-37]

b. No

36. On average, how many days per week and minutes per day do you engage in this kind of exercise? [descriptive text]

a. Enter numbers of days per week [free text]

b. Enter number of minutes per day [free text]

37. When you are exercising in your usual fashion, how would you rate your average level of exertion (degree of effort)? [radio button]

a. Easy

b. Medium (can hold a conversation)

c. Hard (but you can push yourself to continue)

d. Very Hard (cannot hold a conversation)

e. Extremely Hard (out of breath, your body wants to stop the exercise)

38. Do you ***currently*** smoke cigarettes, cigars, or a pipe on a daily basis? [yes/no]

a. Yes [BRANCH 39-40]

b. No [BRANCH 41]

39. What year did you begin smoking? [free text, validation: integer]

40. What is the average number of tobacco products smoked per day since you began using tobacco products? [descriptive text]

a. Enter number of cigarettes per day [free text, validation: integer]

b. Enter number of cigars you smoke per day [free text, validation: integer]

c. Enter number of bowls of tobacco per day [free text, validation: integer]

41. Have you ***ever*** smoked cigarettes, cigars, or a pipe on a daily basis? [yes/no]

a. Yes [BRANCH 42-44]

b. No [proceed to 45]

42. What year did you begin smoking? [free text, validation: integer]

43. What year did you stop smoking? [free text, validation: integer]

44. What was the average number of tobacco products smoked per day when you were smoking?

a. Enter number of cigarettes per day [free text, validation: integer]

b. Enter number of cigars you smoke per day [free text, validation: integer]

c. Enter number of bowls of tobacco per day [free text, validation: integer]

45. Do you ***currently*** use electronic cigarettes (e-cigarettes, vaping)? [yes/no]

a. Yes [BRANCH 46-47]

b. No [BRANCH 48]

46. What year did you begin using electronic cigarettes? [free text, validation: integer]

47. What is the average number of cartridges vaped per day since you began using electronic cigarettes? [free text, validation: integer]

48. Have you ***ever*** used electronic cigarettes (e-cigarettes, vaping)? [yes/no]

a. Yes [BRANCH 49-51]

b. No [proceed to 52]

49. What year did you begin using electronic cigarettes? [free text, validation: integer]

50. What year did you stop using electronic cigarettes? [free text, validation: integer]

51. What was the average number of cartridges vaped per day when you were using electronic cigarettes? [free text, validation: integer]

52. Do you ***currently*** drink alcohol at least once a week? [yes/no]

a. Yes [BRANCH 53, 54, 56]

b. No [BRANCH 58]

53. What year did you begin drinking alcohol at least once a week? [free text, validation: integer]

54. On how many **weekdays** (**Monday through Friday**) do you usually drink alcohol? [radio button: 0, 1, 2, 3, 4, 5, only occasionally] *[Question 55 branches if drinks alcohol on any **weekdays** (1-5, only occasionally]*

55. When you drink on a **weekday**, how many drinks do you usually have? (One drink is equal to 5 ounces of wine, 12 ounces of beer, or 1.5 ounces of liquor) [radio button]

a. 1

b. 2

c. 3

d. 4

e. 5

f. 6

g. >6

56. On how many **weekend days** (**Saturday and Sunday**) do you usually drink alcohol? [radio button: 0, 1, 2, only occasionally] *[Question 57 branches if drinks alcohol on any **weekend days** (1-2, only occasionally]*

57. When you drink on a **weekend day**, how many drinks do you usually have? (One drink is equal to 5 ounces of wine, 12 ounces of beer, or 1.5 ounces of liquor) [radio button]

a. 1

b. 2

c. 3

d. 4

e. 5

f. 6

g. >6

58. Did you ***ever*** drink alcohol at least once a week? [yes/no]

a. Yes [BRANCH 59-61, 63]

b. No

59. What year did you begin drinking alcohol at least once a week? [free text, validation: integer]

60. What year did you stop drinking alcohol at least once a week? [free text, validation: integer]

61. On how many **weekdays** (**Monday through Friday**) did you usually drink alcohol? [radio button: 0, 1, 2, 3, 4, 5, only occasionally] *[Question 62 branches if drinks alcohol on any **weekdays** (1-5, only occasionally]*

62. When you drank on a **weekday**, how many drinks did you usually have? (One drink is equal to 5 ounces of wine, 12 ounces of beer, or 1.5 ounces of liquor) [radio button]

a. 1

b. 2

c. 3

d. 4

e. 5

f. 6

g. >6

63. On how many **weekend days** (**Saturday and Sunday**) did you usually drink alcohol? [radio button: 0, 1, 2, only occasionally] *[Question 64 branches if drinks alcohol on any **weekend days** (1-2, only occasionally]*

64. When you drank on a **weekend day**, how many drinks did you usually have? (One drink is equal to 5 ounces of wine, 12 ounces of beer, or 1.5 ounces of liquor) [radio button]

a. 1
b. 2
c. 3
d. 4
e. 5
f. 6
g. >6

Employment

65. Before the COVID-19 pandemic began in North Carolina, which of the following best described your work situation? Check all that apply. [checkbox]

a. Worked full time [BRANCH]
b. Worked part time [BRANCH]
c. Unemployed [nothing further]
d. Was looking for work/employment [nothing further]
e. Retired [nothing further]
f. Homemaker [nothing further]
g. Student [nothing further]
h. On maternity/paternity leave [BRANCH]
i. On illness/sick leave [BRANCH]
j. On disability [BRANCH]
k. Other, please specify [free text] [BRANCH]

66. Of the job (or jobs) that you held before the COVID-19 pandemic in North Carolina, which description(s) best described your work? Select all that apply [checkbox]

a. Healthcare professional (for example: nurse, physician, advanced practice provider)
b. Other professional (for example: lawyer, pharmacist, executive)
c. Essential service worker (for example: postal/package delivery, grocery)
d. Other service worker (for example: waitstaff, hair stylist, home cleaning)
e. First responder (for example: fire fighter, police, EMT/paramedic)
f. Managerial
g. Administrative support
h. Educator Farming/forestry/fishing/landscape
i. Precision production/craft/repair
j. Operators/fabricators/laborers
k. Military
l. Other, please specify [free text]

67. Before the COVID-19 pandemic began in North Carolina, did you consider yourself self-employed? [radio button]

a. Yes [BRANCH]

b. No

c. Don't know

68. If yes, did you consider yourself a "gig-economy" worker (e.g. like an Uber driver or Task Rabbit handyman)?

a. Yes

b. No

c. Don't know

69. How many years had you spent at your main job prior to the COVID-19 pandemic? [free text, validation: integer]

70. In your main job before the COVID-19 pandemic, how often were you required to work from outside of the home? [radio button]

a. Always

b. Often

c. Sometimes

d. Hardly ever

e. Never

71. In your main job before the COVID-19 pandemic, did your employer offer you any of the following benefits? (select all that apply) [checkbox]

a. Paid sick leave

b. Paid vacation/personal leave

c. Health insurance

d. Disability insurance

e. Retirement plan

Impact of the COVID-19 Pandemic

Please answer the following questions about your household. For this study, household is defined as a residence, and its occupants, regarded as a unit.

72. Has the composition of your household changed since the COVID-19 crisis began in North Carolina? (e.g., a parent moved in to quarantine with you, or your college-aged child moved back home unexpectedly) [yes/no]

a. Yes [BRANCH]

b. No

73. Please explain how your household has changed since the COVID-19 crisis began in North Carolina? [free text]

74. If someone in the household became sick with COVID-19, how well would that person be able to isolate and limit contact with the rest of the household (e.g., separate bedroom, separate bathroom, etc)? [radio button]

a. Extremely well

b. Very well

c. Pretty well

d. Not very well

75. Do any members of your household (other than you) have a job that requires/has required them to leave the home for their jobs? [radio button]

a. Yes [BRANCH]

b. No

c. Don't know

d. Not applicable

76. How worried are you that the member(s) of your household who work outside the home will bring COVID-19 home into your household? [radio button]

a. Extremely worried

b. Moderately worried

c. Slightly worried

d. Not at all worried

77. Thinking about your household as a whole, aside from getting groceries, how often has everyone been staying at home and avoiding interacting with others outside your household? [radio button]

a. Always

b. Most of the time

c. Half of the time

d. Less than half of the time

e. Never

78. How often have you done the following things since the beginning of the COVID-19 pandemic in North Carolina to protect yourself from infection and to keep from spreading infection to others? [matrix] [Responses: Always, Most of the time, Half of the time, Less than half of the time, Never] [recall is "In the last two weeks" for follow up surveys]

a. Worn a face mask when in public places or at work

b. Washed hands and/or used sanitizer frequently

c. Stayed at least 6 feet away from others

d. Avoided large gatherings, public spaces, or crowds

e. Avoided contact with people who could be high risk

f. Avoided food from restaurants, including takeout

g. Worked or studied at home instead of going into an office/classroom

h. Avoided shaking hands or touching people

i. Stayed home if I was sick

j. Wiped down surfaces with disinfectant

79. Since the beginning of the COVID-19 pandemic in North Carolina, have you done any of the following to protect yourself from infection and to keep from spreading infection to others? Select all that apply. [checkbox] [recall is "In the last two weeks" for follow up surveys]

a. Cancelled or postponed planned travel for work

b. Cancelled or postponed travel for pleasure

c. Cancelled or postponed personal or social activities

d. Cancelled a doctor's appointment

e. Stockpiled food or water

f. Followed government guidelines or rules to shelter in place. Specifically, staying at home and limiting contacts with other people

80. How has the COVID-19 pandemic changed how you are saving money? [radio button]

a. I am saving a lot more

b. I am saving a little more

c. I am saving the same

d. I am saving a little less

e. I am saving a lot less

81. How has the COVID-19 pandemic changed how you are spending money? [radio button]

a. I am spending a lot more

b. I am spending a little more

c. I am spending the same

d. I am spending a little less

e. I am spending a lot less

82. How has the COVID-19 pandemic changed how you are borrowing money? [radio button]

a. I am borrowing a lot more

b. I am borrowing a little more

c. I am borrowing the same

d. I am borrowing a little less

e. I am borrowing a lot less

f. Not applicable

83. How has the COVID-19 pandemic changed your reliance on public assistance or charity? [radio button]

a. My use of public assistance or charity has increased a lot

b. My use of public assistance or charity has increased a little

c. My use of public assistance or charity has stayed the same

d. My use of public assistance or charity has decreased a little

e. My use of public assistance or charity has decreased a lot

f. Not applicable

Outlook on the COVID-19 Pandemic

84. On a scale of 0 (not at all informed) to 10 (very well informed), how well informed are you about the COVID-19 pandemic? [matrix]

85. How do you think your total household income will change this year due to the COVID-19 crisis? [radio button]

a. Decrease significantly

b. Decrease slightly

c. Stay the same

d. Increase slightly

e. Increase significantly

86. On a scale of 0 (definitely not going to happen) to 10 (definitely going to happen), how likely do you think it is that your household will run out of money in the next 3 months? [matrix]

87. On a scale of 0 (definitely not going to happen) to 10 (definitely going to happen), how likely is it that you could get financial support from friends or family outside of your house if you ran out of money? [matrix]

88. Suppose that you have a surprise medical bill of $400. Based on your current household financial situation, how will you pay for this expense? (select all that apply) [checkbox]

a. Put it on my credit card and pay it in full at the next statement

b. Put it on my credit card and pay it off over time

c. Pay with money currently in savings/checking

d. Pay with money from a bank loan

e. Pay with money borrowed from family or friends

f. Pay using a payday loan/deposit advance/overdraft

g. Pay by selling something else

h. I wouldn't be able to pay

i. Other, please specify

89. How often is your family getting help with running necessary errands, such as getting groceries or medications? [radio button]

a. Always

b. Most of the time

c. Half of the time

d. Less than half of the time

e. Never

Surveillance Questions

COVID-19 Symptom Monitoring

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Question 90 will render if the participant reported a test with pending result in the preceding survey:

90. You reported being tested for COVID-19 on [test_date] on your last survey, and that the result was pending. What was the final result of your test?

a. Inconclusive

b. Positive

c. Negative

91. ***During the last two weeks,*** have you experienced any of the following symptoms? [descriptive text] [yes to one or more symptoms triggers subsequent questions]

a. Fever (measured by thermometer/self-diagnosed) [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
b. Cough (new or worsening) [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
c. Shortness of breath (new or worsening) [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
d. Fatigue (new tiredness doing normal activities) [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
e. Body aches [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
f. Headache [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
g. Diarrhea [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
h. Sore throat [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
i. Itchy pink or painful eyes [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
j. Runny nose or congestion [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
k. Changes in your sense of smell or taste [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]
l. New rash [yes/no]
   i. Date of symptom onset [free text, validation: mm/dd/yyyy]

[Questions 92 through 105, as applicable based on responses, will branch for YES report of one or more symptoms above]

92. Have you returned to your normal health at this time? [radio button]

a. Yes
b. No
c. Don’t know

93. Did you experience any bias or discrimination due to your symptoms? [radio button]

a. Yes
b. No
c. Don’t know

94. If yes, please describe the bias or discrimination you experienced [free text]

95. When you experienced symptoms, were you worried that you may have COVID-19? [radio button]

a. Yes

b. No

c. Don't know

96. When you experienced symptoms, did anyone tell you that you may have been infected with COVID-19? [radio button]

a. Yes

b. No

c. Don't know

97. Did you seek out testing for COVID-19? [radio button]

a. Yes [Branch]

b. No

c. Don't know

98. Were you tested for COVID-19? [radio button]

a. Yes [Branch]

b. No

c. Don't know

99. What was the date of your test? [date]

100. What was the result of your test? [radio button]

a. Pending

b. Inconclusive

c. Positive

d. Negative

101. When you experienced symptoms, how often did you do the following things to limit the risk of potentially spreading your illness? [matrix] [responses: Always, Most of the time, Half of the time, Less than half of the time, Never]

a. Wore a face mask when in public or at work

b. Washed hands and/or used sanitizer frequently

c. Stayed at least 6 feet away from others

d. Avoided large gatherings, public spaces, or crowds

e. Avoided contact with people who could be high risk

f. Avoided food from restaurants, including takeout

g. Worked or studied at home instead of going into an office/classroom

h. Avoided shaking hands or touching people

i. Stayed home when I was sick

j. Wiped down surfaces with disinfectant

102. When you experienced symptoms, did you do any of the following things to limit the risk of potentially spreading your illness? Select all that apply. [checkbox]

k. Cancelled or postponed planned travel for work

l. Cancelled or postponed planned travel for pleasure

m. Cancelled or postponed personal or social activities

n. Cancelled a doctor's appointment

o. Stockpiled food or water

p. Followed government guidelines or rules to shelter in place. Specifically, staying at home and limiting contacts with other people

103. When you experienced symptoms, what did you do to take care of these symptoms? [descriptive text]

a. Took over-the-counter (OTC) medication [yes/no]

i. If yes, check all that apply: [checkbox]

- NSAIDs or NSAID-containing medications
- Acetaminophen-containing medications
- Other, please specify [free text]

ii. Date when you first took any OTC medication [free text, validation: mm/dd/yyyy]

b. Communicated with a health care provider over the phone [yes/no]

i. Date [free text, validation: mm/dd/yyyy]

c. Visited a health care provider's office [yes/no]

i. Date [free text, validation: mm/dd/yyyy]

d. Visited a retail clinic or pharmacy [yes/no]

i. Date [free text, validation: mm/dd/yyyy]

e. Visited urgent care (FASTMed, etc.) [yes/no]

i. Date [free text, validation: mm/dd/yyyy]

f. Visited the emergency room [yes/no]

i. Date [free text, validation: mm/dd/yyyy]

g. Went to a COVID-19 testing location [yes/no]

i. Date [free text, validation: mm/dd/yyyy]

h. Other [yes/no]

i. Please specify: [free text]

ii. Date [free text, validation: mm/dd/yyyy]

104. When you experienced symptoms, were you admitted to the hospital? [yes/no] [BRANCH]

a. When were you admitted to the hospital? [free text, validation: mm/dd/yyyy]

b. For how many days were you in the hospital? [free text, validation: integer]

105. During your hospital stay, did you require the following interventions? [descriptive text]

a. Extra oxygen in your nose [yes/no]

i. How many days did you use extra oxygen in your nose? [free text, validation: integer]

b. Treatment in the intensive care unit (ICU) [yes/no]

i. How many days were you treated in an ICU? [free text, validation: integer]

c. Mechanical ventilation (intubation or a breathing tube) [yes/no]

i. How many days did you need mechanical ventilation? [free text, validation: integer]

d. If other interventions were required, please briefly specify: [free text]

106. ***During the last two weeks***, have you been tested for COVID-19 for any reason, *other than home testing required if you are part of the C3PI testing group*? [radio button]

a. Yes [BRANCH]

b. No

107. What was the date of your *test*? [date]

108. What was the result of your test? [radio button]

a. Pending

b. Inconclusive [BRANCH]

c. Positive [BRANCH]

d. Negative [BRANCH]

109. What was the date of your ***result***? [date]

General Health & Wellbeing

110. In general, how would you rate your health **over the last two weeks**? [radio button]

a. Excellent

b. Very good

c. Good

d. Fair

e. Poor

111. Are you currently pregnant? [female only, yes/no]

a. Yes

b. No

112. Please indicate how significant a source of stress the COVID-19 pandemic is in your life right now. [radio button]

a. Very significant

b. Somewhat significant

c. Not very significant

d. Not at all significant

113. How serious a problem would you say the COVID-19 pandemic is right now, for you and/or others: [matrix] [Responses: Very serious, Somewhat serious, Not too serious, Not at all serious, Don't know]

a. For you personally

b. For people in your community

c. For people in the United States

d. For people around the world

114. The COVID-19 pandemic causes challenges for some people regardless of whether they are infected. How concerned are you about each of the following things? [matrix] [Responses: Very concerned, Somewhat concerned, Not at all concerned, Don't know, Not applicable]

a. Getting the healthcare I need (including care for mental health)

b. Having a place to live

c. Being able to interact with other people

d. Getting food, water, and other household supplies

e. Getting medication

f. Having transportation to get where I need to go

g. Caring for my family and friends

h. Losing my job

i. Finding a job

j. Being able to feed my family

k. My children's education

Vaccines

115. Did you receive a flu vaccine this flu season (2019-2020)? [radio button] **[BASELINE SURVEY ONLY]**

a. Yes

b. No

c. Don't know

116. How often do you get a flu vaccine? [radio button] **[BASELINE SURVEY ONLY]**

a. Every flu season

b. Most flu seasons

c. Half of the flu seasons

d. Less than half of the flu seasons

e. Never

117. Have you received a flu vaccine for this season (2020-2021)? [radio button]

a. Yes

b. No [BRANCH]

If no,

118. Do you intend to be vaccinated for the flu this season?

a. Yes

b. No

c. Don't know or not sure

119. Do you plan to get a vaccine for COVID-19 when one becomes available? [radio button]

a. Yes

b. No

c. Don't know

120. Have you participated in a COVID-19 vaccine clinical trial? [radio button]

a. Yes

b. No

c. Don't know

121. Have you received a vaccination for COVID-19? [radio button]

a. Yes

b. No

c. Don't know

If yes,

122. What vaccine did you receive? Please select "don't know" if unknown.

a. Pfizer-BioNTech COVID-19 vaccine
   i. Date of first shot
   ii. Date of second shot or "not yet received"
b. Moderna's COVID-19 vaccine (to be added if/when approved)
   i. Date of first shot
   ii. Date of second shot or "not yet received"
c. AstraZeneca's COVID-19 vaccine (to be added if/when approved)
d. Janssen's COVID-19 vaccine (to be added if/when approved)
e. Don't know or not sure

If "not yet received" is indicated for second shot, a question will be incorporated into subsequent surveys to obtain date of second shot when known.

Employment & Risk

123. Has your work situation changed since the COVID-19 pandemic began in North Carolina? [radio button] [at surveys post-enrollment, this question will read: "Has your work situation changed ***in the last 2 weeks***?"]

a. Yes [BRANCH 124-128]

b. No [proceed to 129]

c. Don't know [BRANCH 124-128]

124. Which of the following best fits your current work situation? Select all that apply. [checkbox]

a. Working full time [BRANCH]

b. Working part time [BRANCH]

c. Unemployed [nothing further]

d. Looking for work/employment [nothing further]

e. Retired [nothing further]

f. Homemaker [nothing further]

g. Student [nothing further]

h. On maternity/paternity leave [BRANCH]

i. On illness/sick leave [BRANCH]

j. On disability [BRANCH]

k. Other, please specify [free text] [BRANCH]

125. Of the job (or jobs) that you currently hold, which description(s) best describes your work? Check all that apply. [checkbox]

a. Healthcare professional (for example: nurse, physician, advanced practice provider)

b. Other professional (for example: lawyer, pharmacist, executive)

c. Essential service worker (for example: postal/package delivery, grocery)

d. Other service worker (for example: waitstaff, hair stylist, home cleaning)

e. First responder (for example: fire fighter, police, EMT/paramedic)

f. Managerial

g. Administrative support

h. Educator

i. Farming/forestry/fishing/landscape

j. Precision production/craft/repair

k. Operators/fabricators/laborers

l. Military

m. Other, please specify [free text]

126. Do you consider yourself self-employed? [radio button]

a. Yes [BRANCH]

b. No

c. Don't know

127. If yes, do you consider yourself a "gig-economy" worker (e.g. like an Uber driver or Task Rabbit handyman)?

a. Yes [BRANCH]

b. No

c. Don't know

128. Does your primary employer currently offer you any of the following benefits? (select all that apply) [checkbox]

a. Paid sick leave

b. Paid vacation/personal leave

c. Health insurance

d. Disability insurance

e. Retirement plan

f. Not applicable

129. On a scale of 0 (definitely not going to happen) to 10 (definitely going to happen), how likely is it that you will lose your job because of the COVID-19 pandemic? [matrix, include not applicable] [question does not render if response to employment, whether changed or not, is unemployed, looking for work, retired, homemaker, or student]

130. What do you think is mostly likely to happen to your work hours due to the COVID-10 pandemic? [radio button] [question does not render if response to employment, whether changed or not, is unemployed, looking for work, retired, homemaker, or student]

a. Decrease substantially

b. Decrease a little

c. No change

d. Increase a little

e. Increase substantially

f. Not applicable (not currently working)

131. How often are you required to work from outside of the home currently? [radio button]

a. Always

b. Often

c. Sometimes

d. Hardly ever

e. Never

f. Not applicable (not currently working)

[The following questions will branch if any work required outside of home (answers a-d)]

132. Please indicate how regularly or often the following apply to you when you do work outside of the home? [matrix] [Responses: Always, Very regularly, Somewhat regularly, Not very regularly, Never, Not applicable]

g. I am in close physical contact with co-workers

h. I am in close physical contact with clients

i. I have access to disposable gloves

j. I use disposable gloves

k. I have access to a face mask

l. I use a face mask

m. I wash my hands with soap and water

n. I sanitize my hands with hand sanitizer

133. How worried are you that you will be exposed to COVID-19 at your place of work outside of the home currently? [radio button]

o. Extremely worried

p. Moderately worried

q. Slightly worried

r. Not at all worried

134. How worried are you that you will bring COVID-19 home from your work place to others in your household? [radio button]

s. Extremely worried

t. Moderately worried

u. Slightly worried

v. Not at all worried

135. During the last two weeks, how often have you experienced the following due to your work outside the home during the COVID-19 pandemic? [matrix] [Reponses: Nearly every day, More than half the days, Several days, Not at all]

a. I believed that my job was putting me at great risk

b. I felt extra stress at work

c. I was afraid of falling ill with COVID-19

d. I felt I had little control over whether I would get infected or not

e. I thought I would be unlikely to survive if I were to get COVID-19

f. I thought about resigning because of COVID-19

g. I was afraid I would pass COVID-19 on to others

h. My family and friends were worried that they might get infected through me

i. People avoided my family because of my work

j. I was willing to accept the risks involved because I wanted to help the COVID-19 patients or the public

Survey preferences

136. Would you like to receive future surveys, and possible other study-related communication, via text message? [yes/no]

Please note that message and data rates may apply.

a. Yes [BRANCH]

b. No

c. Don't know

137. If yes, please provide preferred mobile number to receive text messages? [free text, validation: phone number]

Follow-up questions

Questions below [Q138-Q142] apply only to participants that answered having one or more people below the age of 18 in his or her household at enrollment.

138. At enrollment, you reported having one or more people under the age of 18 in your household. Do you still have one or more people under the age of 18 in your household? [radio button]

a. Yes [BRANCH 139-142]

b. No

If yes,

139. How difficult has it been for your household with persons under the age of 18 to adjust to the changes caused by the COVID-19 pandemic?

f. Not difficult

g. Somewhat difficult

h. Very difficult

i. Extremely difficult

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140. To what extent has the COVID-19 pandemic disrupted plans for you and your family for the Summer of 2020? [#temporal]

a. Significant disruption

b. Moderate disruption

c. Little disruption

d. No disruption

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141. What is the format you would prefer for your child or children for the beginning of the school year 2020? [#temporal]

a. In-person attendance as would be expected prior to the COVID-19 pandemic

b. In-person attendance, but with masking and social distancing guidelines in place

c. Some in-person attendance with some remote learning

d. All remote learning, no in-person attendance at school

142. What is the format that seems mostly likely for your children for the beginning of the school year 2020? [#temporal]

a. In-person attendance as would be expected prior to the COVID-19 pandemic

b. In-person attendance, but with masking and social distancing guidelines in place

c. Some in-person attendance with some remote learning

d. All remote learning, no in-person attendance at school

Question **Error! Reference source not found.** below will be asked as an independent survey instrument sent to participants that reported being tested for COVID-19 in a previous survey with pending result:

143. Our records indicate that you reported being tested for COVID-19 in a previous survey, and that the result was pending at that time.

What was the result of your COVID-19 test done on [test_date]?

a. Negative

b. Positive

c. Inconclusive

d. Don’t know/don’t remember