Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Pitt County Community Prevention And COVID-19 Testing Cohort Study

Sponsor/Funding Source: NC Division of Health and Human Services/Division of Public Health

Principal Investigator: Aaron M. Kipp, PhD, MSPH (Person in Charge of this Study)
Institution, Department or Division: East Carolina University, Brody School of Medicine, Department of Public Health
Address: East Carolina Health Institute, 115 Heart Drive, Greenville, NC 27834
Telephone #: (252) 744-2629

Researchers at East Carolina University (ECU) study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to better understand the epidemiology of COVID-19 in Pitt county, including 1) how common infection is over time, 2) the proportion of infections that do not show symptoms, 3) proportion of infections occurring among vaccinated or previously infected individuals, 4) how residents of Pitt county have adhered to prevention measures like social distancing and wearing facemasks, and 5) the impact of the pandemic on their health and wellbeing. You are being invited to take part in this research study because you previously indicated interest in participating in an extended follow-up period for the ComPACT study. The decision to take part in this research is yours to make. By doing this research, we hope to learn more about COVID-19 in Pitt county and how to improve the public health response to the pandemic.

If you volunteer to take part in this research, you will be one of about 175 people to do so. Family members and friends who have not been contacted are not invited to participate at this time.

Are there reasons I should not take part in this research?

You should not volunteer if you do not live in Pitt county, are not at least 18 years old, or feel you cannot commit to the tasks that the research requires. This includes monthly visits to ECU through August 2022 to draw a small amount of blood for testing, completing surveys every two weeks, and collecting a nasal swab for testing every two weeks. The schedule may vary during summer months and this will be communicated to you via phone call or email.

What other choices do I have if I do not take part in this research?

You can choose not to participate.

Where is the research going to take place and how long will it last?

The research will be conducted at the East Carolina Heart Institute (115 Heart Drive, Greenville, NC) which houses the Department of Public Health and clinical space to be used for the study. You will be asked to come to East Carolina Heart Institute once per month for the duration of the study (or on occasion, two times in a month if a prior

study visit was missed and is being made up). These study visits will usually occur on a Thursday afternoon/evening, Friday afternoon/evening, or Saturday morning and are not part of receiving medical or health care. You will be provided with specific instructions prior to your study visits. The total amount of time you will be asked to volunteer for this study is about 2 hours per month.

What will I be asked to do?

You will be asked to do the following:

- Complete a survey two times per month. The surveys will be different lengths of time and cover different topics. Most people will complete the survey online, but if you do not have a computer or smartphone or prefer not to complete the survey online, you will have the option of completing the survey with an interviewer over the phone or at your monthly study visit.
    - ***Annual baseline survey (30-60 minutes):*** Administered each August/September during the study period. This survey will include detailed questions about socio-demographics, ongoing impacts of the COVID-19 pandemic, your current health and well-being, such as anxiety, helplessness, or concern about COVID-19, any symptoms you may have experienced recently. prevention measures you have taken while outside the home, information on household members, and resilience and preparedness for ongoing COVID-19 impact or other emergencies or disasters.
    - ***Long follow-up questionnaire (15-30 minutes):*** Administered at each in-person study visit, this survey will include questions on mental health and wellness, COVID-19 prevention, some questions on physical health including COVID-19 symptoms and treatment, and household members
    - ***Short follow-up questionnaire (10-15 minutes):*** Administered with the bi-monthly nasal swabs collected at home and will include questions on COVID-19 prevention, COVID-19 symptoms and treatment, and household members

- Collect a nasal swab two times per month that will be sent for COVID-19 testing. The swab is inserted about 1 inch into each nostril. Once a month the swab will be collected at your study visit at ECU. You will collect the nasal swab yourself after being instructed on how to do it properly. The second nasal swab you will collect at home. You will be provided with the kit to do the collection and with the materials to mail the swab to be tested. We will provide directions for mailing and study staff will be available at any time to answer questions about collection or mailing.

- Provide about one teaspoon of blood once per month when you come to ECU for your monthly study visit. We will test your blood for COVID-19 antibodies. If there is blood left over, we will store a sample for possible future COVID-19 studies.

When you arrive for each study visit, you will be asked about current symptoms and your temperature will be taken. If you have a fever and/or other COVID-related symptoms, a study clinician may discuss these further with you. The study clinician may determine that it would be more appropriate for you to seek medical care. You may be advised not to complete your study visit that day. In this case, your study visit would be rescheduled for the next study visit date.

What might I experience if I take part in the research?

Any risks that may occur with this research are no more than what you would experience in everyday life. This includes usual risks associated with getting blood drawn, as well as some slight discomfort or irritation in the nose due to the nasal swab. The benefit to you for participating in this study is being tested for COVID-19 every two weeks and testing for COVID-19 antibodies (evidence of prior infection) every month. The information gained by doing this research may also help prevent COVID-19 in Pitt county and also the public health response to COVID-19.

Will I be paid for taking part in this research?
We will be able to pay you for the time you volunteer while being in this study. By volunteering in this study, you may receive up to $25 each month according to the following schedule:

- Completing the annual baseline survey (August/September) and attending the corresponding in-person study visit to provide a nasal swab and blood sample ($25)
- Completing the long-follow-up survey and providing a nasal swab and blood sample at each additional in-person study visit ($15)
- Completing each at-home survey and nasal swab 2 weeks after your study visit ($10)

If you do not already have one, we will give you a special debit card (called a Greenphire ClinCard) at your first study visit. We will be able to add payment to that card during the study period and will pay for the time spent completing study tasks. For example, if you miss the at-home survey and nasal swab, but attend the in-person study visit that month, we will add $15 to your study Greenphire ClinCard for that month. If you complete the at-home survey and nasal swab but do not come to the in-person study visit, we will add $10 to your study Greenphire ClinCard that month. If you complete both, we will add $25 to your study Greenphire ClinCard that month. To receive these payments, you must complete the survey portion. There is no penalty for not completing the nasal swab or providing the blood sample. There will be times when weather or other factors make it difficult to complete the tasks.

Over the course of the study, from September 2021 through August 2022, you may receive up to $675. This includes up to $225 you may have already received for your participation to date, plus up to another $450 for participating now through August 2022. You are not required to provide your Social Security Number to participate in this study. However, to receive a study participation payment totaling $100.00 or more for this study, you will need to provide your Social Security Number to the University so that the University and you comply with tax reporting laws. If you are/have received payment from participating in other studies, you also will need to provide your Social Security Number. If you do not provide your Social Security Number, we cannot provide you a study participation payment totaling $600 or more in a calendar year. However, you may still choose to participate in this study but you will not be able to receive a study participation payment totaling $600.00 or more within a calendar year unless you provide my Social Security Number. ECU is responsible for keeping track of funds that are provided during research studies. You will provide this information at your first study visit.

Additionally, all participants who complete at least 90% of all study tasks (survey, NMT, and venipuncture) will be entered into a raffle for one of two $100 gift cards to Amazon or Walmart at the end of year 1 of the study (approximately April 2021) and again at the end of year 2 of the study (approximately August 2022).

Will it cost me to take part in this research?
It will not cost you any money to be part of the research. However, you are responsible for your own transportation to the study visits. Study personnel will consider transportation challenges on a case by case basis as we do not want lack of transportation to prevent you from participating.

Who will know that I took part in this research and learn personal information about me?
ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the North Carolina Department of Health and Human Services (DHHS), and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.

- If your nasal swab sample is positive, the Pitt County Health Department will contact you, so that you and your close contacts can be instructed to isolate or quarantine according to their instruction.
- The research study team who is conducting the study.

When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization.

The individuals who will use or disclose your identifiable health information for research purposes include the principal investigator and the research study team. Individuals who will receive your identifiable health information for research purposes include the principal investigator and the research study team, laboratories that are testing your nasal swab and blood sample (the State Laboratory for Public Health and ECU Department of Cardiovascular Sciences Laboratory), institutional officials (for audit purposes), the UMCIRB, and possibly researchers at Duke University and University of North Carolina conducting similar COVID-19 projects. The type of information accessed for this research study includes your name, age, race/ethnicity, sex, date of birth, date of specimen collection, and test result. The information will be used and disclosed in such a way as to protect your identity as much as possible; however, confidentiality cannot be absolutely guaranteed. Someone receiving information collected under this Authorization could potentially re-disclose it, and therefore it would no longer be protected under the HIPAA privacy rules (federal rules that govern the use and disclosure of your health information). There is not an expiration date for this Authorization.

You may not participate in this study if you do not consent to this PHI authorization. You may revoke (withdraw) this Authorization by submitting a request in writing to Dr. Aaron Kipp (person in charge of the study). However, the research team will be able to use any and all of the information collected prior to your request to withdraw your Authorization.

How will you keep the information you collect about me secure? How long will you keep it?

ECU requires research information to be stored securely in password protected databases behind a "firewall." For this project, all data that will be collected will be collected in a research database approved by ECU and UMCIRB for storing personal identifying data. The only people with the passwords to access the study database are people on the research study team who need to be working with your personal information (for example to call you, or email you, about upcoming study tasks, or to enter your test results). Your personal identifying data will be removed from all data before conducting any analyses. Other people not on the research study team may analyze the data, but they will not be able to know your personal identifying information. The Principal Investigator and trained, approved research staff are the only people with access to data that can be linked to you. Data will be retained for 7 years.

What if I decide I don't want to continue in this research?

You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. If you decide you no longer want to participate, please call or email us if you no longer wish to participate and we will make sure you are no longer contacted about the study. We will still inform you of any positive test results samples taken before you stopped participating. However, there will not be any further payments after you stop participating and we will not be able to provide further testing.

Who should I contact if I have questions?

The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at (252) 744-2629 during normal business hours. You may also call the study phone number at (252) 744-4033 or email the study (compactstudy@ecu.edu) at any time.

If you have questions about your rights as someone taking part in research, you may call the University & Medical Center Institutional Review Board (UMCIRB) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you have

questions about the sharing of PHI related to this research study, call the Principal Investigator at 252-744-2629. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at East Carolina University at 252-744-5200.
If you would like to report a complaint or concern about this research study, you may call the Director for Human Research Protections, at 252-744-2914.

Is there anything else I should know?

The quality of the research findings is very dependent on your commitment to participate the entire study period.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and, after such removal, the information or biospecimens could be used for future research studies, including other COVID-19 studies, or distributed to another investigator for future research studies without additional informed consent from you or your Legally Authorized Representative (LAR). However, there still may be a chance that someone could figure out the information is about you.

The following research results will be provided to you:

- For positive nasal swab results, the study physician will call you within 24-48 hours of the test result.
- For positive antibody tests or a change in antibody status from positive to negative, you will be contacted by phone or email within 7 days.

We will not report negative test results to you. However, at any point in time, you may inquire about any lab result and this will be communicated to them. Official lab result documents will also be provided upon request. It is your responsibility to communicate any study results to your healthcare provider that you feel they should know.

Will I receive anything for the use of my private identifiable information or identifiable biospecimens?
If the research conducted on your private identifiable information or identifiable biospecimens leads to a commercially valuable product, you will not be eligible for any of the profits either because it will be impossible to identify the information or biospecimen that led to the product or because you are transferring ownership of that sample.

Will my identifiable biospecimen be used for whole genome sequencing?
Whole genome sequencing is the process of determining the complete DNA sequence of an individual at a single time. However, further analysis must usually be performed to provide any biological or medical meaning of this sequence. For this research, whole genome sequencing will not occur. If for future studies, we decide to conduct genome sequencing, we will contact you and give you the option of providing or declining consent to use your sample.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I authorize the use and disclosure of my health information for this study in the way that has been described in this form
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, which includes the PHI authorization, and it is mine to keep.

***Title of Study**: The* Pitt County ComPACT Study

Participant's Name (PRINT)	**Signature**	**Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

Person Obtaining Consent (PRINT)	**Signature**	**Date**