Official Title:	COVID-19 Serologic Strategies for Skilled Nursing Facilities (CERO)
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Study Number:	20-01281
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Date of the Document:	• 8/16/2021

INFORMED CONSENT FORM (FOR FACILITY STAFF)

Sponsor / Study Title:	**National Institute on Aging / "COVID-19 Serologic Strategies for Skilled Nursing Facilities"**
Protocol Number:	**FY20 Supplement2 Chodosh/ s20-01281**
Principal Investigator: (Study Doctor)	**Joshua Chodosh, MD, MSHS, FACP**
Telephone:	**212-263-6768 (24 Hours)**
Address:	**Terence Cardinal Cooke** **1249 Fifth Avenue** **New York, NY 10029** **Mary Manning Walsh** **1339 York Avenue 72nd Street** **New York, NY 10021**

If you are an employee of this skilled nursing home/facility, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this facility. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

KEY INFORMATION

You are invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to be in this study. This research study is studying new approaches to improve safety and quality of care for skilled nursing home (SNF) residents and for the facility staff who care for them. The goal of this study is to decrease the risk of COVID-19 exposure between facility staff and residents. Our goal is to see whether we can reduce the number of COVID-19 cases using a new approach compared to nursing units where we do not use this approach. This is a National Institutes of Health (NIH) sponsored research study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain any words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. You may also decide to discuss this study and this form with your family, friends, or family doctor. If you decide to take part in this study, you must sign this form. We will also give you a copy of this form - for you to keep.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you currently work at a skilled nursing facility that is participating in this study.

As we are sure you are aware, the COVID-19 pandemic has greatly impacted the United States and it has been especially devastating for older persons living in skilled nursing facilities (SNFs). If there is a second wave of infections, we hope our work will help to improve your safety and that of the residents you care for. Taking part in this study will help us understand your experience during the pandemic. If you are being asked to participate, you work on a unit where we are introducing a staff-resident pairing strategy that will potentially decrease exposure to COVID-19 and decrease the likelihood of COVID-19 infection. Your facility will participate in this pilot study for the next 12 months. Our study staff will help administrators, the facility staff and residents you take care of to improve facility safety and support resident quality of care. As we assist facility staff with the strategy we will test, we would like to collect information on how it is working.

We believe that someone who has antibodies to COVID-19 from vaccination or had at one time a nasal swab that indicated they had the infection (and has now recovered) is someone who is unlikely to get the infection again or to pass it on to someone else when they are in close contact. We don't know whether trying to limit close contact between two people who are` still at risk of infection can reduce how often a new infection occurs.

The nursing facility will use this strategy on some units to have facility staff assigned to care for certain residents based on what we know about whether or not someone (facility staff or resident) had the infection before.

The purpose of this study is to:

- Test whether it is possible to pair facility staff with residents for their daily needs based on whether or not either person (the facility staff person or the resident) has already had a COVID-19 infection or not
- To see whether this strategy can reduce the number of new COVID-19 infections for residents and for facility staff

Up to 100 subjects will participate in this study. Up to 20 residents and 30 SNF staff per unit, with two units in each participating nursing facility (Mary Manning Walsh and Terrence Cardinal Cooke, both under ArchCare).

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately 12 months. If you choose to participate in the study, we will ask you to give written consent before you participate in the study. Your agreement to participate is to audio-record a qualitative interview which will be transcribed. The recording and transcription will be de-identified to ensure your privacy. We will also offer you the opportunity to participate in an additional brief (5- to 10-minute) survey that has questions about you.

If you choose to participate, we will provide you with additional compensation. Your personal information will not be linked to you and responses will remain anonymous.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Participate in a qualitative interview which will be conducted by a research assistant from the NYU School of Medicine. The interview will last approximately 30 minutes.
- Complete optional brief 5-10-minute survey. Additional compensation will be provided.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

This is a minimal risk study. The only interventions in this study that are cohort assignments based on COVID-19 testing. On any unit included in this study, facility staff-resident assignments may be determined by prior PCR results or antibody testing and your assignments will be at the discretion of your unit's management just as it would be on any unit. This will occur whether or not you decide to participate in this study. Your consent to participate is only for the interview. We will monitor for any concerns and complaints at the resident, family or facility staff level. We will conduct monthly check-ins with unit managers for complaints and will inquire and record any safety concerns at all facility leadership/stakeholder meetings. While this study poses no more than "minimal risk" to subjects, like any study there may be some risk.

Some risks associated with participation are:

1. Psychosocial risk: When asked questions by study staff there is potential to feel frustrated, embarrassed, fear, or guilt that is might be experienced when participating in studies.
2. Loss of confidentiality: Subject loss of confidentiality is another potential risk in clinical trials and with data collection. However, we have taken precaution to protect your information. No data are collected which can identify you. All files which may link you to your data are stored separately and kept under lock and key or encrypted and password-protected. All study staff are well trained to maintain your confidentiality.

If you would like to talk to someone about your feelings about this study, have any questions, or if any unforeseen or unanticipated issues arise for you during the course of this study, you are encouraged to contact the study doctor at the telephone number listed on the first page of this consent document.

All names will be removed from all the information collected. If any member of the research team has or is given information about elder or dependent abuse, he or she is required to report it to the authorities.

UNFORESEEN RISKS

As with any study, some risks may be unanticipated. If any issues do arise, please contact the study doctor at the telephone number listed on the first page of this consent document.

ALTERNATIVES TO PARTICIPATION
You may choose not to participate in this research study. Participation in research is entirely voluntary. Your decision to participate or not will not impact your employment in the nursing facility.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
You will receive a $50 gift-card as compensation for your participation in this study. An additional $25 gift-card will be provided if you also wish to complete the brief survey.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against facility records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from the sponsor: National Institutes of Health, Brown University, New York University Grossman School of Medicine.
- The research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study subjects),
- Government regulatory authorities including, the US Food and Drug Administration (FDA) and other regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By providing written consent, you consent to the collection, access, use and disclosure of your information as described above.

FUTURE RESEARCH STUDIES
Your private information or biospecimens collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

CERTIFICATE OF CONFIDENTIALITY
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

COSTS
There will be no charge to you for your participation in this study.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:

  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00045956.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your current or future employment. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Principal study doctor may ask you to have some end-of-study tests for your safety.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

Name of Subject (Print)	Date
Signature of Subject	
Name of Person Obtaining Consent (Print)	
Signature of Person Obtaining Consent	Date