2021H0220: COVID-19 in a Big University Setting (CBUS)

Final Rule (For office use only)

Study 2021H0220 - Identification

Title of Study*	COVID-19 in a Big University Setting (CBUS)
Principal Investigator*	Abigail Norris Turner (norris-turner.1)
Study Department*	Medicine | IM Infectious Diseases (CC11289)
Department Signer	Susheela Tridandapani (Signed: 06/03/2021)

Principal Investigator - Abigail Norris Turner

Contact Information

Email: ant@osumc.edu
Phone: (614) 3663510

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)
American STD Association

Academic Information

Professor (6640)
Medicine | IM Infectious Diseases (cc11289)
Medicine (Medicine_CCH6)
100% FTE

PI Eligibility

✓ Eligible

Type of Research

Select the appropriate option below based on the type of review required for the research.

Exempt research: This option should be selected for research that involves human subjects that is not subject to regulations requiring IRB review and approval. Final determination is made by ORRP staff.

Expedited or full IRB-reviewed research: This option should be selected for review by the Biomedical Sciences, Behavioral and Social Sciences, or Cancer IRBs at Ohio State including research reviewed through either expedited or full board processes. This option should also be selected for any research which will be ceded to another non-Ohio State IRB, such as WIRB, NCI CIRB, or another external institution.

Don't know: This option should be selected if the investigator is uncertain whether the research is exempt or should be reviewed by an IRB.

What type of review is required for your project?*

- □ Exempt research
- ■ IRB-reviewed research (includes WIRB, NCI, CIRB, and other external IRB review)
- □ Don't know (screening questions to determine if exempt research)

Review Board

Research at Ohio State involving human subjects that requires Institutional Review Board (IRB) review is reviewed by one of three university IRBs or one of multiple external IRBs, including Western IRB (WIRB), National Cancer Institute Central IRB (CIRB), and Nationwide Children's Hospital (NCH) IRB. Board assignments are made to ensure that proposed research receives appropriate scientific or scholarly review by individuals with the qualifications to determine that the rights and welfare of research participants are protected. Final board assignment is determined by ORRP.

Selection of one of the three Ohio State IRBs below will connect to the initial review of human subjects research.

Selection of one of the external (non-Ohio State) IRBs will connect to an external review application which provides the necessary information for ORRP staff to perform pre-screening of the application to determine that institutional requirements have been met (e.g., COI disclosure, education) and that the research meets the conditions necessary to be forwarded for external IRB review.

Select the board to review this research.*

- □ Ohio State Behavioral and Social Sciences IRB
- ■ Ohio State Biomedical Sciences IRB
- □ Ohio State Cancer IRB
- □ National Cancer Institute Central IRB (CIRB)
- □ Nationwide Children's Hospital IRB
- □ Western IRB (WIRB)
- □ Other external IRB

Multi-site Study

Multisite research includes projects or studies that involve collaboration with sites or individuals external to Ohio State. The IRB must determine whether external sites or personnel need IRB approval in order to participate in study activities.

EXAMPLES OF MULTI-SITE RESEARCH:

- Ohio State is the lead institution of a group of sites participating in the same research project, where all sites are recruiting subjects and administering research interventions.
- An Ohio State investigator is participating in a research project, where another institution is the lead institution.
- Ohio State is the IRB of record for one or more other sites participating in a research project.

EXAMPLES OF NON-MULTI-SITE RESEARCH:

- An Ohio State investigator is conducting research at a local elementary school that involves recruiting participants and performing study interventions, where no school employees are engaged in the research.
- An Ohio State investigator and research staff interact with clients at a local pharmacy, and a letter of support from the pharmacy is in place.

Is this a multi-site study?*	□ Yes ■ No

Location of Research

Research to be conducted at locations other than approved performance sites may require a letter of support or another institution's approval if personnel are engaged. See OHRP Engagement Guidance or contact ORRP at irbagreements@osu.edu or 614-688-8457 for more information.

Ohio State Approved Research Sites

Ohio State Columbus Campus

Address	410 W. 10th Avenue 1144N Doan Hall, Division of Infectious Diseases

Columbus, OH

Domestic Research Sites – Non-Ohio State Locations

You have listed no alternate domestic research sites.

International Research Sites

You have listed no international research sites.

Study Personnel

Enter all Ohio State study team members below. External collaborators will be entered on a different page. Study team members should only be listed in one category (i.e., PI, co-investigator, or key personnel).

Co-investigators and key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.

Additional contacts can also serve in another role on the project.

All individuals listed as Ohio State study team members will have access to all submitted information, including completion status of team members' administrative and training requirements (CITI, RCR, COI disclosure), and may edit submissions on behalf of the principal investigator.

Electronic signatures are required of all Ohio State investigators named on the submission.

Study Team

Co-Investigator - Karen Dannemiller

Contact Information

Email: dannemiller.70@osu.edu
Phone: (614) 2924031

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Associate Professor (9M) (2320-9M)
Engineering | Civil Environmental and Geodetic Engineering (cc11832)
Engineering (Engineering_CCH6)
70% FTE

Associate Professor (9M) (2320-9M)
Public Health | Environmental Health Science (cc10493)
Public Health (Public_Health_CCH6)

30% FTE

Activities Performed

Data analysis/interpretation; Reporting results; Manuscript preparation;

Co-Investigator - Maria Gallo

Contact Information

Email: gallo.86@osu.edu
Phone: (614) 6882145

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)
Relias Media

Academic Information

Professor (9M) (6640-9M)
Public Health | Division of Epidemiology (cc10495)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Co-Investigator - Alison Norris

Contact Information

Email: norris.570@osu.edu
Phone: (614) 6883219

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Associate Professor (9M) (2320-9M)
Public Health | Division of Epidemiology (cc10495)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Co-Investigator - Jose Bazan

Contact Information

Email: bazan.8@osu.edu
Phone: (614) 2935667

Conflict of Interest (COI)

Academic Information

Associate Professor - Clinical (2337)
Medicine | IM Infectious Diseases (cc11289)

✓ Completed (Expires: 06/30/2022)

Medicine (Medicine_CCH6)
50% FTE

Physician (6380)
Health Sciences | FGP IM Infectious Diseases (cc11307)
Health Sciences (Health_Sciences_CCH6)
50% FTE

Activities Performed

Protocol development/study design; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Co-Investigator - Mikkel Quam

Contact Information

Email: quam.7@osu.edu
Phone:

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2021)
Umea University

Academic Information

Assistant Professor - Practice (3160)
Public Health | Division of Epidemiology (cc10495)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

Protocol development/study design; Recruitment; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Co-Investigator - Joseph Tien

Contact Information

Email: tien.20@osu.edu
Phone: (614) 2925893

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2021)

Academic Information

Professor (9M) (6640-9M)
Arts and Sciences | Mathematics (cc12396)
Arts and Sciences (Arts_and_Sciences_CCH6)
100% FTE

Activities Performed

Protocol development/study design; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Access participant Protected Health Information (PHI);

Co-Investigator - William Miller

Contact Information

Email: miller.8332@osu.edu
Phone: (614) 2922516

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2021)
American Sexually Transmitted Diseases Association; UNC Project-Malawi; UNC Project-Vietnam; SESH Global

Academic Information

Professor (6640)
Public Health | Division of Epidemiology (cc10495)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

Protocol development/study design; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Co-Investigator - Richard Robinson

Contact Information

Email: robinson.2346@osu.edu
Phone: (614) 2934164

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Associate Professor (2320)
Medicine | School Biomedical Sciences
Microbial Infection and Immunity (cc12837)
Medicine (Medicine_CCH6)
100% FTE

Activities Performed

Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Access participant Protected Health Information (PHI);

Key Personnel [redacted]

Contact Information

Email [redacted].
Phone:

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2021)

Academic Information

Graduate Research Associate (4894)
Public Health | Division of Epidemiology (cc10495)
Public Health (Public_Health_CCH6)
50% FTE

Activities Performed

Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Access participant Protected Health Information (PHI);

Key Personne [redacted]

Contact Information

Ema [redacted].
Phone:

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Student Associate (7969)
Public Health | College Administration (cc10504)
Public Health (Public_Health_CCH6)
70% FTE

Activities Performed

Protocol development/study design; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Key Personne [redacted]

Contact Information

Ema [redacted].
Phone [redacted]

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Student Assistant (7968)
Public Health | College Administration (cc10504)
Public Health (Public_Health_CCH6)
70% FTE

Activities Performed

Protocol development/study design; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

External Co-Investigators & Key Personnel

Enter the names of external collaborators who are engaged in the research. Only external personnel whose activities will be covered by an Ohio State IRB should be included.

"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Ohio State University. See OHRP Engagement Guidance or contact ORRP at irbagreements@osu.edu or 614-688-8457 for more information.

External Collaborators

You have listed no external collaborators.

Funding and Financial Conflicts

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact ORRP for more information.

Is the research funded or has funding been requested?*

- ■ Yes
- □ No
- □ Pending

Sponsors

Anonymous

Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study?*

- □ Yes
- ■ No
- □ Pending

Provide a copy of the grant application or funding proposal.

Uploaded Files

CBUS funding proposal 20210513.docx

Uploaded by Abigail Norris Turner on 05/13/2021

Financial Conflict of Interest

All Ohio State investigators and key personnel must have a current COI disclosure (updated as necessary for the proposed research) before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights and royalties from such rights. For more information, see Office of Research Compliance COI Overview and eCOI.

Please indicate if any Ohio State University investigator (including principal or co-investigator), key personnel, or their immediate family members has a financial conflict (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research.

Select 'none' if no financial conflicts exist.*

- ■ None
- □ Mikkel Quam
- □ Joseph Tien
- □ Abigail Norris Turner
- [redacted]
- □ Karen Dannemiller
- □ Maria Gallo
- □ Alison Norris
- □ Jose Bazan
- [redacted]
- □ William Miller
- □ Richard Robinson

Conditions required for expedited IRB review

The Federal Regulations establish two main criteria for an expedited review:

a. The research may not involve more than "minimal risk." "Minimal risk" means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46.102(i) and 21 CFR 56.102(i)).
b. The entire research project must be consistent with one or more of the federally defined categories.

The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects.

Investigators are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review (i.e., expedited or convened) utilized by the IRB.

Protocols involving the collection, storage, and/or distribution of data and/or specimens for future research uses do not qualify for expedited IRB review. Convened review is required.

For more information regarding the expedited review procedures, see the Expedited Review Procedures policy.

Are you requesting **Expedited Review**?*

■ Yes □ No

Expedited Review Categories

Select the appropriate category(ies) for expedited review that describe the proposed research. Check all that apply. If the research meets the conditions for expedited review, the review of the protocol will be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. See 45 CFR 46 and 21 CFR 56 for more information.

The categories in this list apply regardless of the age of the participants, except as noted.

Category #1

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
b. Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

□ Apply for category #1

Category #2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
b. From other adults and children (defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.45 CFR 46.402(a)), considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

□ Apply for category #2

Category #3

Prospective collection of biological specimens for research purposes by non-invasive means.

a. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

□ Apply for category #3

Category #4

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

□ Apply for category #4

Category #5

Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or

diagnosis).

■ Apply for category #5

Category #6

Collection of data from voice, video, digital or image recordings made for research purposes.

□ Apply for category #6

Category #7

Research made on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

□ Apply for category #7

Institutional Approvals

Check all that apply and provide applicable documentation.

■ No institutional approval

Comprehensive Cancer Center (CCC) Clinical Scientific Review Committee (CSRC)

Approval or exemption required prior to IRB review for all cancer-related research.

□ Comprehensive Cancer Center (CCC) Clinical Scientific Review Committee (CSRC)

Institutional Biosafety Committee (IBC)

Approval required prior to IRB review for research involving biohazards (recombinant DNA, infectious or select agents, viruses, toxins), gene transfer, or xenotransplantation.
Note: Laboratories processing clinical research samples (e.g., blood, serum, tissue, urine,

feces, saliva, bile), must be registered with the IBC. As applicable, contact IBCinfo@osu.edu to confirm laboratory registration.

□ Institutional Biosafety Committee (IBC)

Summary, Background, and Objectives

Summarize the proposed research using **non-technical** language that can be readily understood by someone outside the discipline. **Use complete sentences (limit 300 words).***

The project will analyze student COVID-19 testing data collected from August 1, 2020 through June 1, 2021, as part of OSU's COVID-19 testing program. The study will examine the characteristics of students who acquired COVID-19, including initial infection and re-infection; it will track the emergence over time of SARS-CoV-2 variants of interest and variants of concern; it will assess key timeframes of disease and immunity, including the reversion to PCR-negative after a positive test, and drop in antibody levels following a positive test; it will quantify important epidemiological parameters, including the average number of close contacts of a given case who go on to acquire COVID-19 ("secondary attack rate") and the observed reproductive number "R0"; and it will pair case data from specific weeks with dust surveillance from the same time period, to determine whether this approach could work to identify cases in the future.

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. **Use complete sentences (limit 300 words).***

University students are a distinct and important population to study risk of acquisition of SARS-CoV-2, the virus that causes COVID-19. Their age, corresponding health and immune status, and behavioral patterns are correlated with high spread but low morbidity and mortality. This project leverages the extensive COVID-19 testing data collected through campus COVID-19 testing efforts from August 1, 2020 through June 1 2021, to explore a number of critical research questions. OSU's was one of the largest systematic COVID-19 testing programs in the world for the 2020-21 academic year, with the number of weekly tests being run greater than many US states. This project has high probability of producing useful scientific results with very low risk to human subjects (as the data already exist).

List the objectives and/or specific scientific or scholarly aims of the research study.*

The study will evaluate: 1. Demographic and time-varying behavioral correlates of infection and reinfection with SARS-CoV-2, overall and following vaccination; 2. Demographic and time-varying behavioral correlates of SARS-CoV-2 infection with specific viral variants; 3. Time to negative PCR test <90 days, among students testing positive, overall and by viral variant; 4. Time to drop in antibody levels <90 days, among students testing positive, overall and by viral variant; 5. Secondary attack rate of SARS-CoV (the proportion of close contacts who convert to a case within 14 days of index case exposure); 6. Observed reproductive number (R); and 7. Correlation between campus- and building-level SARS-CoV-2 prevalence and detection of SARS-CoV-2 in dust.

Upload research protocol*

Uploaded Files

CBUS protocol 20210601.docx

Uploaded by Abigail Norris Turner on 06/01/2021

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.*

No interventions or interactions will be performed solely for this research study. All proposed analyses use existing data collected for OSU's public health surveillance efforts. This study is a retrospective analysis of existing data collected for public health surveillance to communicate generalizable knowledge on related to COVID-19 risk and related questions. We will analyze public health surveillance data based upon information and records contained within the 'Contact Tracing Data Environment-Research and Analytics Environment' (CDTE-RAE). This is the secured dataset used for maintaining and communicating information related the University's response to the COVID-19 pandemic. This comprises laboratory records as well as information derived from case investigation and contact tracing in response to the ongoing COVID-19 pandemic and OSU's response to it.

Check all research activities and/or components that apply.*	□ Anesthesia (general or local) or sedation □ Audio, video, digital, or image recordings □ Biohazards (e.g., rDNA, infectious agents, select agents, toxins) □ Biological sampling (other than blood) □ Blood drawing □ Coordinating center □ Data repositories (future unspecified use, including research databases) ■ Data, not publicly available □ Data, publicly available (e.g., census data, unrestricted data sets) □ Deception □ Devices □ Diet, exercise, or sleep modifications □ Drugs or biologics (including dietary supplements/ingredients) □ Emergency research □ Focus groups □ Food supplements □ Gene transfer □ Genetic testing □ Internet or e-mail data collection □ Magnetic resonance imaging (MRI) □ Materials that may be considered sensitive, offensive, threatening, or degrading □ Non-invasive medical procedures (e.g., EKG, Doppler) □ Observation of participants (including field notes) □ Oral history (does not include dental or medical history) □ Placebo □ Pregnancy testing □ Program Protocol (Umbrella Protocol) □ Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) □ Randomization ■ Record review (which may include PHI) □ Specimen research □ Stem cell research □ Storage of biological materials (future unspecified use, including repositories) □ Surgical procedures (including biopsies) □ Surveys, questionnaires, or interviews (group) □ Surveys, questionnaires, or interviews (one-on-one) □ Other (Specify)
Provide data collection forms, subject material, subject diaries, and/or other	Uploaded Files CBUS variable list.docx *Uploaded by Abigail Norris Turner on 06/25/2021*

instruments, if applicable. Do not include case report forms for multi-site industry-initiated or cooperative group studies.

Provide surveys, questionnaires, interview guides, and/or focus group guides, if applicable.

Uploaded Files

No files have been uploaded.

Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable.

Uploaded Files

No files have been uploaded.

Duration

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any. For studies with no subject time involvement, such as record review studies with a waiver of consent or observational studies, enter 'not applicable.'*

Not applicable.

Number of Participants

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove to be eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University approval.*

71,500

□ Unlimited participant numbers

Total number of participants* 71500

Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).*

The OSU total autumn 2020 enrollment was 67957 students. In case there were transfers or other changes impacting enrollment during the academic year 2020-2021, we increased the allowable sample size by a margin of about 5%.

Participant Population

Specify the age(s) of the individuals who may be included in the research:*

18 years of age and older

Specify the participant population(s). Check all participant groups that apply.*

■ Adults
□ Adults with impaired decision-making ability
□ Children
□ Neonates (uncertain viability/nonviable)
□ Non-English speaking
□ Pregnant women/fetuses – only if pregnant women will be intentionally recruited and/or studied.
□ Prisoners
□ Student research pools (e.g., psychology, linguistics)
■ Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.*

Participants are students who underwent COVID-19 testing as part of OSU's public health surveillance testing program, August 1, 2020 through June 1, 2021. As noted elsewhere, university students are a distinct and important population to study risk of acquisition of SARS-CoV-2, the virus that causes COVID-19. Their age, corresponding health and immune status, and behavioral patterns are correlated with high spread but low morbidity and mortality.

Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status?*

■ Yes □ No

Explain the criteria and reason(s) for each exclusion.*

Only students aged 18 and older are included.

Are any of the participants likely to be vulnerable to coercion or undue influence?*

□ Yes ■ No

Participant Identification, Recruitment and Selection

Participant Identification

Provide evidence that you will be able to recruit the necessary number of participants to complete the study.*

The retrospective nature of this study requires no recruitment to complete the study.

Describe how potential participants will be identified (e.g., advertising, individuals known to the investigators, record review). Explain how the investigator(s) will gain access to this population, as applicable.*

Several personnel on this project have access to the data to be analyzed through their involvement in OSU's public health surveillance efforts, in particular, the Comprehensive Monitoring Team (CMT) and the Case Investigation and Contact Tracing Team (CICTT).

The data exist in the secure Contact Tracing Data Environment of the Research and Analytics Environment (CTDE-RAE), which is accessible only by research team members via a secure server. The analysis will also be conducted on the secure server by key personnel with appropriate security and confidentiality training to work with these datasets.

Participant Recruitment and Selection

Select investigator(s) and/or key personnel who will recruit participants or identify records and/or specimens.*

■ Mikkel Quam
□ Joseph Tien
□ Abigail Norris Turner
[redacted]
□ Karen Dannemiller
□ Maria Gallo
□ Alison Norris
□ Jose Bazan
[redacted]
□ William Miller
□ Richard Robinson

Describe the process that will be used to determine participant eligibility.*

COVID-19 testing records for all OSU students are already present in the Contact Tracing Data Environment of the Research and Analytics Environment (CTDE-RAE).

Describe the recruitment process, including the setting in which recruitment will take place. Enter 'not applicable' if the research involves only record review and no participant interaction.*

Not applicable

Explain how the recruitment process respects potential participants' privacy.*

No recruitment will occur as part of this project. However, participants' privacy will be respected by conducting all analyses on a secure server and using coded data (stripped of individually-identifying information).

Provide copies of proposed recruitment materials (e.g., ads, fliers, website postings, and recruitment letters).

Uploaded Files

No files have been uploaded.

Provide copies of consent materials used during the recruitment process (e.g., oral/written scripts).

Uploaded Files

No files have been uploaded.

Incentives to Participate

For more information regarding incentives for participation, see the ORRP policy, Recruiting Methods, Recruiting Materials, and Participant Compensation.

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, classroom credit) to participate in the research study?*

□ Yes ■ No

Alternatives to Study Participation

Other than choosing not to participate, are there any alternatives to participating in the research?*

□ Yes ■ No

Informed Consent Process

□ Informed Consent - Form

Indicate the consent process(es) to be used in the study. Check all that apply.*

□ Informed Consent - Verbal Script/Online
□ Informed Consent – Addendum
□ Alteration of Consent Process
□ Alteration of Parental Permission
□ Assent - Form
□ Debriefing Script
□ Assent - Verbal Script/Online
□ Parental Permission - Form
□ Parental Permission - Verbal Script/Online
□ Translated Consent/Assent - Form(s)
□ Waiver of Assent
■ Waiver of Consent Process
□ Waiver of Consent Documentation
□ Waiver of Parental Permission
□ Waiver of Parental Permission Documentation

Select the investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.*

■ None
□ Mikkel Quam
□ Joseph Tien
□ Abigail Norris Turner
[redacted]
□ Karen Dannemiller
□ Maria Gallo
□ Alison Norris
□ Jose Bazan
[redacted]
□ William Miller
□ Richard Robinson

Who will provide consent or permission (i.e., participant, legally authorized representative, parent and/or guardian)?*

■ Not Applicable

Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.*

■ Not Applicable

Explain how the possibility of coercion or undue influence will be minimized in the consent process.*

■ Not Applicable

Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?*

□ Yes ■ No

Will any other consent forms be used (e.g., for clinical procedures such as MRI, surgery, etc.)?*

□ Yes ■ No

Waiver of Consent Process

Complete the questions below to request a waiver of the consent process. NOTE: Waivers of consent do not apply to greater than minimal risk research.

For additional guidance, see HRPP policy Informed Consent Process and the Elements of Informed Consent and the IRB Reviewer Reference Sheets - Appendix 1.

Is the research (or demonstration project) subject to the approval of state or local government officials and designed to study public benefit or service programs or procedures for obtaining benefits under those programs, changes in or alternatives to those programs or procedures, or changes in methods or levels of payment for benefits or services under those programs?*

□ Yes ■ No

Explain how the research (or research activities to which the waiver of consent applies) involves no more than minimal risk.*

This project involves extremely low risk to potential participants. The data were already collected and analyzed as part of the university's public health surveillance and response to

COVID-19. For this project, analyses will take place on a secure server accessible only to study personnel. Although identifiable data will be used to merge relevant datasets, analyses will only take place using a coded version of the dataset, further protecting participant confidentiality.

Explain why the waiver will not adversely affect the rights and welfare of the participants.*

As part of campus surveillance during the 2020-21 academic year, students already consented to being tested repeatedly for COVID-19 and to disclosure of their test results to both the university and the state (per federal surveillance/reporting guidelines). (See full consent/HIPAA statement in subsequent sections of this application). We are combining these data with information otherwise available through OSU, including student demographics, residence, and other factors (see variable list in subsequent sections of this application). As students have already consented to the collection and use of these separate sources of data, we do not believe that combining and analyzing them adversely affects their rights or welfare. In addition, by analyzing only coded data and on a secure server, we further affirm that participants' rights and welfare shall not be adversely affected.

Explain why the research could not 'practicably' be carried out without the requested waiver.*

OSU processed more than 700,000 samples for COVID testing, from up to 71,500 persons. It is not practical to contact this number of individuals to request their permission to analyze the data.

Explain why (for research involving identifiable private information/biospecimens) the research could not 'practicably' be carried out without using such information or biospecimens in an identifiable format.*

All epidemiological analyses will be conducted using coded data. We cannot scrub all identifiers from the data prior to merging because of the need to link datasets containing different elements (e.g. laboratory data with student demographic data). Only study team members who already have permission to access the identifiable data (e.g. those involved with the surveillance efforts of the CMT and/or the CICTT) will view identifiable data.

Will the participants be provided with additional pertinent information after participation (e.g., debriefing)?*

□ Yes ■ No

Explain why or why not.*

No findings from this project will be relevant at the individual level. Participants have already been notified of their SARS-CoV-2 status following each test.

Privacy of Participants

Describe the provisions to protect the privacy interests of the participants.*

This study protects the privacy interests of participants in the following ways: - No reports or publications will include identifiable data; - Any subgroup sample size of 5 or less will not be reported out; - All data are stored on, and all analysis will be conducted on, a secure server with access limited only to the research team; and - All staff are trained on the importance of protecting participant privacy.

Does the research require access to personally identifiable, private information?*

■ Yes □ No

Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, medical records, etc.).*

In order to create the coded dataset for analysis, personally identifiable information will be viewed in COVID-19 testing data as well as OSU administrative records (for example age, campus residential status, year of education, involvement in athletics or Greek life, etc.).

Confidentiality of Data

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Information for this study will be stored on a secure server with controlled access only by research staff. All data are electronic; there are no paper records.

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

■ Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

■ Not Applicable

Indicate what will happen to identifiable data at the end of the study*

□ Identifiable data will not be collected
□ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
■ Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
□ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

Certificate of Confidentiality

If your study is not NIH-funded, will you be requesting a Certificate of Confidentiality from the NIH?

□ Yes ■ No

HIPAA Research Authorization

PHI is health information that is individually identifiable and created or held by a covered entity. Health information is considered individually identifiable when it contains one or more of the 18 HIPAA identifiers or when there is a reasonable basis to believe the information can be used to identify an individual.

For more information, see 45 CFR Parts 160 and 164 or Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.

Authorization: although similar to informed consent, an authorization focuses on privacy risks and permission to specifically use or disclose PHI.

Partial waiver of HIPAA authorization: permits access to and use of PHI for recruitment purposes, prior to obtaining authorization. Specifically, it allows for the identification and, as appropriate, contact of potential participants to determine their interest in study participation. Note: A partial waiver does not permit retention or other use of the information beyond its original purpose.

Full waiver of HIPAA authorization: waives the requirement to obtain an individual's authorization for the use of PHI for a particular research project (such as a retrospective chart review), or for a specific portion/population of the research (such as a waiver that applies only to review of health records of patients previously treated that are used as controls).

Alteration of HIPAA authorization: allows a change in certain authorization requirements, while still requiring authorization for the use of PHI. Examples include making an exception to the required language in an authorization form or eliminating the requirement to obtain a signed authorization (e.g., authorization provided over the phone).

This information below is un-editable and can only be revised with the submission of an amendment after approval or withdrawal of the continuing review submission.

For more information, please see http://orrp.osu.edu/irb/irbforms/hipaa/.

Is individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements to be accessed, used, or disclosed in the research study?*

■ Yes □ No

Indicate how authorization requirements will be met (check all that apply).*

□ Written Authorization
□ Partial Waiver (for identification and recruitment purposes only)
■ Full Waiver (authorization will not be obtained)

□ Alteration (written authorization will not be obtained or all required elements will not be included)

Full Waiver of HIPAA Research Authorization

Complete this page to request a full waiver of HIPAA authorization to access, use, or disclose Protected Health Information (PHI) for the proposed research. A Full waiver of HIPAA authorization waives the requirement to obtain an individual's authorization for the use of PHI for a particular research project (such as a retrospective chart review), or for a specific portion/population of the research (such as a waiver that applies only to review of health records of patients previously treated that are used as controls).

List the source(s) of PHI applicable to the waiver (e.g., OSUWMC Information Warehouse, eResults, physician's office records, clinical database, etc.). Be as specific as possible.*

This study leverages data collected from August 1, 2020 through June 1, 2021, through OSU's COVID surveillance program. Data are captured in the OSU Contact Tracing Data Environment / Reporting and Analytics Environment (CTDE/RAE). The CTDE/RAE contains results from COVID-19 testing from all participating students over the course of the year, as well as variables describing students (demographics, residence, involvement with athletics or Greek life, and other factors). The universe of viewable variables in the CTDE/RAE are viewable in the attached Excel spreadsheet, although only a small number of these will be used for the proposed research.

Describe the PHI that will be accessed (viewed) for the research under the waiver (e.g., medical record number, health history, diagnosis, test results, etc.).*

PHI visible in the CTDE/RAE include all information related to COVID testing (date, result, etc.) as well as other identifying information such as name, address, date of birth, demographic characteristics, etc. The universe of viewable variables in the CTDE/RAE are viewable in the attached Excel spreadsheet, although only a small number of these will be used for the proposed research.

Describe information that will be recorded. Be as specific as possible, including date ranges, when applicable. Spell out all abbreviations.*

When creating the analysis database for this project, we will exclude PHI whenever possible. For analysis purposes, we will retain dates of COVID-19 testing, dates of isolation, dates of quarantine, and participant date of birth (to compute age).

Select all study team members who will access medical information:*

- ■ Mikkel Quam
- ■ Joseph Tien
- ■ Abigail Norris Turner
- [redacted]
- □ Karen Dannemiller
- ■ Maria Gallo
- ■ Alison Norris
- ■ Jose Bazan
- [redacted]
- ■ William Miller
- ■ Richard Robinson

Provide a copy of the data collection form(s) used (e.g., Excel spreadsheet, etc.) to record the information above.*

Uploaded Files

CBUS variable list.docx

Uploaded by Abigail Norris Turner on 06/25/2021

Explain why access to and/or use of the PHI is essential to conduct the research.*

To address our research objectives, we need to know each participant's COVID-19 testing history and related variables.

Explain how the PHI described above represents the minimum necessary information to accomplish the objectives of the research.*

The purpose of the research is to answer several questions related to COVID-19 risk of infection and reinfection. Thus, COVID-19 testing information essential to accomplish the objectives of the research.

Explain how the access, use, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.*

As all data (PHI and other data) are already collected and stored in a secure server location, and project staff already have access to those data because of their roles in the

CMT and/or the CICTT, the risks of PHI disclosure are not meaningfully increased through the use of these data for this project.

Describe your plan to protect identifiers and associated PHI (or links to identifiable data) from improper use or disclosure, including where PHI will be stored (include both the building/room number and/or specific server information), what security measures will be applied, and who will have access to the information. Describe the safeguards used for electronic records, hard copy records, or both, as applicable.*

PHI data were already collected as part of OSU's COVID-19 testing program. The data/information/records are contained securely within the Contact Tracing Data Environment/Research and Analytics Environment (CTDE-RAE), which was specifically designed to protect private information during OSU's COVID-19 response, including results of surveillance testing. This server is managed by OSU-OCIO and a contracted service from Amazon Athena. Amazon Athena is specially designed to securely handle data containing PHI. This is a double authenticated secured environment with restricted access to the secured datasets used for maintaining and communicating laboratory records, case investigation and contact tracing, and comprehensive monitoring and response to the ongoing COVID-19 pandemic. From these records and only within this environment, the queries are run to construct the coded datasets for study analysis.

Will identifiers (or links to identifiable data) be destroyed?*

□ Yes
■ No
□ N/A - Will not record identifiers or create links or codes to connect data

Provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.*

For public health surveillance purposes, identifiable data will continue to be retained within the Contact Tracing Data Environment. For research reasons including data quality checks and de-duplication of records, it is prudent to retain individual identifiers in that secure environment. Identifiable data within the double-authentication secured environment are accessible to only those study personnel who already have access to participant PHI as necessary for their role in OSU's COVID-19 response (e.g. through the CMT or CICTT).

Explain why a waiver (instead of written authorization) is needed to conduct the research (e.g., no longer in regular contact with individuals, scientific validity, etc.).*

We are requesting a waiver for four reasons: 1. This study will use data that was collected previously for another purpose and is used in a form where participant data is no longer individually identifiable; 2. The use of these data poses no additional risk to the participants other than that to which they are already aware (i.e. the potential loss of privacy) through the testing consent process previously described; 3. A critical component of the OSU COVID surveillance program is student COVID testing. Students can opt out of COVID testing (albeit under very specific circumstances); however, once a student has provided the specimen for COVID-19 testing and received test results, the participants' data has already been included in the dataset and is analyzed as part of the routine public health surveillance operations at the University; and 4. It is not practicable to obtain a written research authorization from more than 70,000 people.

Reasonably Anticipated Benefits

List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.*

There are no direct benefits to individual participants.

List the potential benefits that society and/or others may expect as a result of this research study.*

This study will benefit society in that it will produce new knowledge characterizing various correlates and parameters of COVID-19 risk in university students. Even as COVID-19 recedes, the findings can be applied to future emerging public health threats.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.*

There are no new risk, harms, and/or discomforts that is expected as a result of the proposed study given that the study's analysis is on coded data already collected and archived for public health surveillance. All analyses will be conducted using coded data in a secure data environment. No individual participant contact is anticipated. When accessing or analyzing data on individuals' personal health and/or demographic information, there is a

risk of breach of confidentiality. The likelihood of a breach is extremely low, given the restricted access protocols already in place.

Describe how risks, harms, and/or discomforts will be minimized.*

Security and confidentiality protocols already in place throughout OSU's pandemic response, particularly surrounding data access, remain in place. All analyses will be conducted using coded data in a secure data environment. No individual participant contact is anticipated. Because study personnel involved in this project have been working on OSU's pandemic response all year, they are already well trained on minimizing risks, harms and discomfort to potential participants.

Assessment of Risks & Benefits

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.*

As result of this retrospective analysis, there is no anticipated increased risk to participants beyond what they have already consented and experienced to during the testing process; however, there is substantial anticipated benefit to the making public novel surveillance analysis tools which can assist public health response in this and future transmission events among other populations utilizing or considering the utility of serial testing and tracing strategies.

Monitoring

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described for the study beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)?*

□ Yes ■ No

Participant Costs/Reimbursements

Are there any additional costs that may result from study participation (e.g., parking, study drugs, diagnostic tests, etc.)?*

□ Yes ■ No

Uploaded Files Review

To access or upload a file, click on a page below.

Domestic Site Documentation

No documents have been added for review.

International Site Documentation

No documents have been added for review.

Grant Applications

CBUS funding proposal 20210513.docx **05/13/2021**

Research Protocol

CBUS protocol 20210601.docx **06/01/2021**

Data collection forms and/or other instruments

CBUS variable list.docx **06/25/2021**

Subject Information

No documents have been added for review.

Surveys and/or questionnaires

No documents have been added for review.

Recruitment materials (e.g., ads, fliers, website postings, and letters)

No documents have been added for review.

Other Files

No documents have been added for review.

Other Files/Comments

This page should be used to provide ORRP or the IRB with additional information related to the current submission.

The general comments text area can be used to provide clarification to ORRP staff or the IRB members.

The general upload box below should be used to upload any additional documents necessary for this submission that were not already captured previously in the form. Examples of documents which may be uploaded include the detailed cover letter response for modifications or deferrals, IRB approvals for external sites at the time of continuing review, or a memo to IRB reviewers from the investigator.

Uploaded Files

No files have been uploaded.

Additional comments for this submission.

This protocol uses similar data and methods as the recently-approved project 2021H0189.

COVID-19 in a Big University Setting (CBUS)
Study Protocol
June 2021

Summary
University students are a distinct and important population to study risk of acquisition of SARS-CoV-2, the virus that causes COVID-19. Their age, corresponding health and immune status, and behavioral patterns are correlated with high spread but low morbidity and mortality. This project leverages the extensive COVID-19 testing data collected through campus COVID-19 testing efforts from August 1, 2020 through June 1 2021, to explore a number of critical research questions. All data to be analyzed for this work already exist, having been collected as part of the COVID-19 response by the OSU Continuous Monitoring Team (CMT) and the OSU Case Investigation and Contact Tracing Team (CICTT).

Background

OSU COVID-19 public health surveillance
OSU tested students from August 1, 2020 through June 1, 2021 as part of the university's plan to manage COVID-19 during the 2020-2021 academic year. OSU's COVID-19 control plan consisted of widespread asymptomatic public health surveillance testing as well as testing of symptomatic students. Positive cases were contained by being isolated for 10 days from the date of the test, in a designated isolation location. The CICTT initiated contact tracing procedures, and individuals identified as close contacts of a positive case were quarantined for 10-14 days (the timeframe shifted midyear from 14 to 10 days, in keeping with developing public health containment measures). This 'test and trace' strategy sought to test each of the students residing on campus weekly, with those living off-campus testing approximately every 2-4 weeks; when clusters of two or more linked cases were detected, the CICTT recommended more frequent targeted testing of specific student groups. At the end of the Spring 2021 semester, testing frequency increased to twice per week for some student populations.

Procedures

Design. This study will use existing COVID-19 testing data from students participating in the OSU COVID-19 surveillance program (https://safeandhealthy.osu.edu/testing) between August 1, 2020 and June 1, 2021, to assess epidemiological trends in risk of COVID-19 infection or reinfection and related questions.

Participants. Study participants are OSU students connected to the Columbus campus, 18 years or older, who were tested for SARS-CoV-2 as part of the OSU COVID-19 testing program between August 1, 2020 and June 1, 2021. OSU Fall 2020 enrollment was 67,957 students in the published statistical summary. In case of transfers or other changes impacting enrollment, we increased the anticipated sample size by a margin of about 5% to n=71,500.

Recruitment. Participants will not be individually recruited for this study. Rather, this study will use existing already collected data, analyzed retrospectively.

Informed consent and HIPAA Authorization. We anticipate no direct contact with participants for this project, thus are requesting waivers of both the requirement for informed consent and the requirement for a HIPAA research authorization. At the time of testing, students provided electronic consent to the following statement: "I voluntarily authorize [testing provider] to use and/or disclose my COVID-19 test results to The Ohio State University as part of the ongoing surveillance testing related to COVID-19 community spread. I understand that my COVID-19 test results are considered Protected Health Information (PHI) and no payment will be exchanged for disclosure of my test results. I further understand that I have the right to revoke this authorization, in writing, by sending written notification to: Office of Compliance and Integrity-Privacy, 650 Ackerman Road, Columbus, Ohio 43202. I understand that PHI used or disclosed pursuant to this authorization may be redisclosed by the recipient and its confidentiality may no longer be protected by federal or state law. I consent to the use of electronic signature and understand that my documenting consent below, I have affirmatively executed this authorization."

Data Collection, Storage and Security

The OSU testing data resides in the secure Contact Tracing Data Environment / Research and Analytics Environment (CTDE-RAE). This resource has both strict access monitoring and double-authentication access via a virtual machine. All analysis will be conducted in this secure environment. Most study personnel already have required permissions to access to the data to be used for this research, due to their ongoing involvement with either the CMT or the CICTT.

Datasets to be used in these analyses:

1. Dates and results of all tests [including qualitative (positive/negative/indeterminate) and quantitative (cycle threshold) results, and data on variants of interest/concern] for all students from August 1, 2020 through June 1, 2021;
2. Dates and location of isolation and quarantine;
3. Student demographic characteristics (e.g. age, race, ethnicity, income, sex, etc.);
4. Student academic characteristics (e.g. major, year in school, etc.);
5. Student residence (on-campus vs. off-campus; when on-campus, only building will be recorded); and
6. Student activities (e.g., involvement in athletics, Greek life, etc.)
7. Vaccination status
8. Dates of last exposure to a case, and links between cases and exposed contacts as recorded by the CICTT
9. Symptoms

Data in the CTDE-RAE are stored in .csv datasets. While these datasets contain PHI, analysis datasets for this project will be stripped of individually-identifying data after merging. Research records will be distinguished by a study-assigned ID number not derived from a PHI element

(e.g. not based on a medical record number, birthdate or student ID number). No identifiable information will be removed from the secured CTDE-RAE environment during the conduct of this research. No identifiable results will ever be released in publications or reports, and any subgroup sample size of 5 or less will not be reported out, in order to protect student privacy.

Data analysis

Broadly, this project aims to assess epidemiological factors associated with risk of SARS-CoV-2 infection or reinfection, and to describe epidemic characteristics, in this student population during the 2020-21 academic year. Specific objectives include to assess:

1. Demographic and time-varying behavioral correlates of infection and reinfection with SARS-CoV-2, overall and following vaccination;
2. Demographic and time-varying behavioral correlates of SARS-CoV-2 infection with specific viral variants;
3. Time to negative PCR test, among students testing positive, overall and by viral variant;
4. Time to drop in antibody levels, among students testing positive, overall and by viral variant;
5. Secondary attack rate of SARS-CoV-2 (the proportion of close contacts who convert to a case within 14 days of index case exposure);
6. Observed reproductive number (R); and
7. Correlation between campus- and building-level SARS-CoV-2 prevalence and detection of SARS-CoV-2 in dust.

The analytic approach and analysis population will vary depending on the specific question being asked.

#1: To assess demographic and time-varying behavioral correlates of infection and reinfection with SARS-CoV-2, we will use conventional time-to-event hazard regression models. We will assess both unadjusted and adjusted effects of various student characteristics on the risk of acquisition of SARS-CoV-2 infection and separately, re-infection. If we have sufficient data, we will also assess the effect of vaccination on COVID-19 acquisition in this student population.

#2: This objective will use a similar analytic approach as #1, except that we will narrow the outcomes of interest to be specific viral variants of interest and variants of concern. These variants categories are dynamic but refer broadly to SARS-CoV-2 strains which are observed to be more infectious or more virulent than others, and thus required enhanced public health focus.

#3: To quantify the time to convert to SARS-CoV-2 PCR negative, the analysis population is the cohort of students with confirmed dates of positive PCR. The analysis is a descriptive time series. Sub-analyses would stratify by a) severity of symptoms at time of infection and b) by coding PCR results as continuous, using cycle threshold to observe changes in viral load. The analysis population would exclude those with re-infections.

#4: Among those with prior confirmed COVID-19, we will assess how long it takes for students' anti-SARS-CoV-2 antibody levels to drop to non-detectable. The analysis population is again the cohort of students with confirmed dates of positive PCR, and the analysis is again a descriptive time series characterizing changes in antibody levels from the week prior to infection, through the infection period, and again beginning 12 weeks post-infection. (Students found to have COVID-19 were exempt from testing for 12 weeks, thus we will not have antibody data for the 12 weeks after their infection until they re-entered the testing pool. Sub-analyses would stratify by severity of symptoms at time of infection.

#5: To calculate the secondary attack rate of SARS-CoV-2 (the proportion of close contacts who convert to a case within 14 days of index case exposure), we will define close contacts as individuals who have been within 6 feet of a positive case for 15 minutes or longer over a 24-hour period within the infectious period of the case. We will use logistic regression to evaluate whether the secondary attack rate differs by the following index case attributes: 1) symptomatic status at the time of case notification; 2) gender; 3) year in program (e.g. 1-4 for undergraduates, years of training for graduate and professional students); 4) residence type; and 5) academic area of study. We will calculate odds ratios that are unadjusted and adjusted for all factors of interest. We will use multiple imputation for missing data.

#6: The observed reproductive number (R). R is the average number of secondary cases per infectious case in a population made up of both susceptible and non-susceptible people. The effective reproduction number can be estimated by the product of the basic reproductive number and the fraction of the host population that is susceptible (x).

#7: We will assess the correlation between campus- and building-level SARS-CoV-2 prevalence and detection of SARS-CoV-2 in dust. SARS-CoV-2 is influenced by time spent in location, building layout, and mask use. Co-I Dr. Dannemiller has developed an assay that identifies SARS-CoV-2 in dust; this approach is similar to wastewater monitoring but has both logistical and feasibility advantages. We will assess correlation between building-specific identification of SARS-CoV-2 in dust with test data for students in the same buildings in the same time periods as dust collection.

Assessment of risks and benefits

This project is retrospective and uses only existing data. As such, the anticipated increased risk to participants (beyond what they have already consented to as part of OSU's COVID monitoring program) is negligible. However, there is substantial anticipated benefit to better understanding of the factors affecting COVID-19 risk in this and similar populations.