2021H0189: Analyzing Repeat COVID-19 Testing Data for OSU Students

Final Rule (For office use only)

Study 2021H0189 - Identification

Title of Study*	Analyzing Repeat COVID-19 Testing Data for OSU Students
Principal Investigator*	Grzegorz Rempala (rempala.3)
Study Department*	Public Health | Division of Biostatistics (CC10499)
Department Signer	Kellie Archer (Signed: 05/06/2021)

Principal Investigator - Grzegorz Rempala

Contact Information

Email: rempala.3@osu.edu
Phone: (614) 2920006

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Professor (9M) (6640-9M)
Public Health | Division of Biostatistics (cc10499)
Public Health (Public_Health_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	1841 Neil Ave Cunz Hall-Building 293, Office 380E 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 - 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; Assess participant eligibility; Data collection/entry/coding; Data analysis/interpretation; Reporting results; Manuscript preparation; Maintain regulatory documentation; Access participant Protected Health Information (PHI);

Key Personnel - Matthew Wascher

Contact Information

Email: wascher.1@osu.edu
Phone:

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Post Doctoral Scholar (8806)
Public Health | Division of Biostatistics (cc10499)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

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

Key Personnel - Patrick Schnell

Contact Information

Email: schnell.31@osu.edu
Phone: (614) 2925274

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2021)
Cincinnati Children's Hospital Medical Center; Infor; Merck & Co., Inc.

Academic Information

Assistant Professor (9M) (0918-9M)
Public Health | Division of Biostatistics (cc10499)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

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

Key Personnel - Joseph Tien

Contact Information

Academic Information

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

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2021)

Associate Professor (9M) (2320-9M)
Arts and Sciences | Mathematics (cc12396)
Arts and Sciences (Arts_and_Sciences_CCH6)
100% FTE

Activities Performed

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

Key Personnel - Wasiur Rahman Khuda Bukhsh

Contact Information

Email: khudabukhsh.2@osu.edu
Phone:

Conflict of Interest (COI)

✓ Completed (Expires: 06/30/2022)

Academic Information

Post Doctoral Scholar (8806)
Public Health | Division of Biostatistics (cc10499)
Public Health (Public_Health_CCH6)
100% FTE

Activities Performed

Data analysis/interpretation; Reporting results; Manuscript preparation;

Key Personnel - 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

Associate Professor (2320)
Medicine | IM Infectious Diseases (cc11289)
Medicine (Medicine_CCH6)
100% FTE

Activities Performed

Protocol development/study design;

Key Personnel - Yuhan Pan

Contact Information

Email: pan.387@osu.edu
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

Recruitment; Assess participant eligibility; Data collection/entry/coding; Data analysis/interpretation; 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

□ Yes

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

■ No
□ Pending

Provide a copy of the grant application or funding proposal.

Uploaded Files

No files have been uploaded.

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
□ Grzegorz Rempala
□ Mikkel Quam
□ Matthew Wascher
□ Patrick Schnell
□ Joseph Tien
□ Wasiur Rahman Khuda Bukhsh
□ Abigail Norris Turner
□ Yuhan Pan

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 research project is seeking to analyze the student COVID-19 surveillance data collected already as part of the COVID-19 (non-research) response by the OSU Comprehensive Monitoring Team. The specific objectives of the work proposed here are twofold (a) to present for peer review the analysis of OSU COVID-19 testing data in the context of developed methods and (b) to make publicly available the computational tools developed by OSU modeling team so that they can be utilized and possibly improved upon by other research groups working on COVID-19 monitoring.

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).***

Several modeling and evaluation approaches were developed to assess the feasibility and impact of potential mitigation strategies such as frequent, random testing of asymptomatic individuals, contact tracing and isolation, caps on in-person class sizes. Some notable approaches involved full-scale agent- or network-based simulations parameterized using information from local epidemics and run forward to yield predictions through the end of an academic term, and thus naturally faced challenges stemming from a lack of transmission data in the campus setting and quickly increasing uncertainty in predictions of future trajectories, see, e.g., Christensen et al. (2020); Gressman and Peck (2020); Panovska- Griffiths et al. (2020); Chang, Crawford and Kaplan (2020). Nevertheless, these studies were able to robustly highlight the need for

large-scale, frequent, randomized (if not comprehensive) testing of asymptomatic individuals (Gressman and Peck, 2020; Losina et al., 2020), which was adopted by many colleges and universities that ultimately held in-person instruction during the subsequent autumn semester. OSU like many others utilized a serial testing approach to assess the transmission among their student populations during the 2020-2021 academic year. The analysis of the OSU surveillance testing program's data has been of sufficient scale to provide useful insight into COVID-19 prevalence among OSU students and generalizable knowledge could be derived from the monitoring approach taken by the University. Largely, this analysis has already been conducted and would not generate any additional risk or harm to human subjects through the further retrospective analysis and subsequent dissemination of the novel methods and tools innovated upon during the pandemic response.

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

The specific objectives of the work proposed here are (a) to present for peer review the analysis of OSU COVID-19 testing data in the context of developed methods and (b) to make publicly available the computational tools developed by OSU modeling team so that they can be utilized and possibly improved upon by other research groups working on COVID-19 monitoring.

Upload research protocol*

Uploaded Files

IRB-COVID_v3.pdf

Uploaded by Grzegorz Rempala on 05/24/2021

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 were/are to be performed solely for the research study.

This study will be a retrospective analysis of a small subset of existing data collected for public health surveillance to communicate generalizable knowledge on novel modeling methodologies. 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, information derived from case investigation and contact tracing collected in response to the ongoing COVID-19 pandemic.

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

Uploaded Files

datafile_example_IRB.xlsx

Uploaded by Mikkel Quam on 05/22/2021

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.*

71500 students

□ 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 is listed as 67957 students in the university published statistical summary. 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 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 within the public health surveillance testing program conducted at OSU in the 2020-2021 academic year. The purpose of the research is to present novel methodology for monitoring infection dynamics with university population that are participating in serial test and trace interventions to quell outbreaks. The analysis proposed relies on data from adult students within the OSU surveillance testing pool.

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 records of students 18 years old and older will be included in the analysis for this study; those younger than 18 are excluded.

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 requested data are already in existence due to student testing requirements. 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 of the key personnel and Co-PI Quam have access to this population/data /records as part of the public health surveillance conducted by the OSU Comprehensive Monitoring Team (CMT) and Case Investigation and Contact Tracing Team (CICTT). The coded analytical dataset are derived from records within the Contact Tracing Data Environment of the Research and Analytics Environment (CTDE-RAE), accessible only by research team members via a secured server, who for public health surveillance and response already necessitate access to relevant PHI. The coded modeling and statistical analysis is also conducted on the secured 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.*

- ■ Grzegorz Rempala
- ■ Mikkel Quam
- ■ Matthew Wascher
- ■ Patrick Schnell
- ■ Joseph Tien
- □ Wasiur Rahman Khuda Bukhsh
- □ Abigail Norris Turner
- ■ Yuhan Pan

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

Participant eligibility will be assessed due to student enrollment, age, campus residency (where applicable), and results of COVID-19 surveillance testing during the 2020-2021 academic year. Co-PI Quam along with key personnel Wascher, Schnell, Pan and Tien will have access to the data utilized to determine participant eligibility as part of their

contributions to the OSU Comprehensive Monitoring Team's modeling and analytics section as well as OSU Infectious Disease Institute's Modeling Team (which additionally includes PI Rempala and key personnel Khuda Bukhsh). Inclusion criteria includes any student testing positive through the surveillance testing program. The timing of the positive and most recent negative test data will be retrieved/queried from the public health surveillance testing program records and then individuals' records will be coded, to construct the dataset for analysis.

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.*

The secured server environment and steps to code data for this retrospective analysis acknowledge the sensitivity of data of this nature and respect the need to maintain individual participant privacy at all steps within testing, tracing, and tracking of COVID-19 as part of the University's public health surveillance and response, as well as the subsequent currently proposed research oriented analysis.

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

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

□ Informed Consent - Form
□ 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
□ Grzegorz Rempala
□ Mikkel Quam
□ Matthew Wascher
□ Patrick Schnell
□ Joseph Tien
□ Wasiur Rahman Khuda Bukhsh
□ Abigail Norris Turner
□ Yuhan Pan

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 retrospective analysis does not add any additional potential risk to the participant. The data was already collected and analyzed as part of the university's public health surveillance and response to COVID-19.

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

As part of the OSU COVID screening program, each participant will have already consented to the following HIPAA AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION 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." It should be noted the above language is edited slighlty according to the test provider, VAULT Health, OSUMC/AMSL, SHS, etc. all of which contributed to the testing conducted for the same purposes during the 2020-2021 academic year. Additional consent beyond that which subjects have already agreed (i.e. the above HIPAA AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION statement) is not being sought for this study and we are requesting a waiver of consent for the following reasons: (1) our study will use existing data collected and shared with the university for public health surveillance, which is queried, coded, stored, and accessed by study personnel on a secured server by individuals who already have access to it; (2) the use of these data poses no additional risk to the participant other than that to which they are already aware (i.e. the potential loss of privacy). The intent of our study is also related to surveillance of COVID19 community spread, to which participants have already consented per the statement above at the time of testing.

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

The university processed more than 700,000 samples for COVID PCR testing, sometimes over 7,000 in a single day. It is not practical to contact this number of individuals per day to request their permission to analyze the data generated for these samples for the up to 71,500 persons, who may have contributed data. Furthermore and related to the nature of our project, which is connected to modeling and analysis of surveillance data, only retaining people who consented would skew the data and thus introduce errors in our data interpretation and the utility of the study for generalizable knowledge.

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.*

At the point of analysis the identifiable information will have been removed and only be available in a coded manner. Because linking most recent past negative results with the first positive results at the individual level is necessary to established the timeline of potential transmission, individual identifiable datasets will be initially queried to generate the research dataset. Only study team members, who already have access to the information in the identifiable format will be contributing to the coding/de-identification process, which will take place within the secured server access to the contact tracing data environment.

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

□ Yes ■ No

Explain why or why not.*

No actionable data at the individual level will be obtained for participants in this study (i.e. the participants will have already been notified of their SARS-CoV-2 status prior to our retrospective analysis of existing data), so no further pertinent information for sharing with the participants will come directly from this project.

Privacy of Participants

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

Our study will protect the privacy and security of participant data according to OSU policy and applicable law, including HIPAA and Ohio State law. Data for this project will be obtained only on participants who have signed the HIPAA AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION statement detailed above. All reports and publications generated by our study will not reveal identifiable participant data. The project will limit access to participant data by "roles" in compliance with minimum necessary standards. Appropriate measures will be taken to implement administrative, technical, and physical safeguards to protect participant data. Individuals associated with this protocol are trained in the protection of participant privacy; such training will be modified as necessary to address privacy and security issues arising from new systems and processes created by study.

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.).*

Public health surveillance testing program and related data records contained within the Contact Tracing Data Environment needed for this study include the participants' COVID-19 testing results history, age and campus residential status at the time of testing positive. Like other data sources containing educational and medical records, many other more detailed elements of identifiable private information is necessarily contained

within the Contact Tracing Data Environment, but only limited coded elements are needed for this particular research study dataset. Using programming software on a secured server, we will query from the identifiable data sources to determine eligibility and assemble the coded research datasets, but this will be constructed without the need to observe personally identifiable private information at the participant level. The codex will be stored on a secured server accessible to Co-I Quam and key personnel involved in the programming the queries used for determining eligibility.

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.*

Our study will protect the privacy and security of participant data according to OSU policy and applicable laws. Any reports and publications generated by our study will only present unidentifiable participant data. The project will limit access to participant data by "roles" in compliance with minimum necessary access standards. Appropriate measures will be taken to implement administrative, technical, and physical safeguards to protect participant data. Individuals associated with this protocol are trained in the protection of participant privacy; such training will be modified as necessary to address privacy and security issues arising from new systems and processes created by study.

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.*

Ohio State University Reporting and Analytics Environment-Contact Tracing Data Environment (CTDE/RAE) containing results data from the public health surveillance testing program. Individual participants' results of COVID-19 testing (data containing PHI) applicable to the waiver is shared with the University and maintained for public health surveillance according to aforementioned HIPAA authorization. Study Personnel Co-I Mikkel Quam, and key personnel Matthew Wascher, Joseph Tien, Patrick Schnell and Yuhan Pan have access to this environment in their roles as members of the Ohio State's Comprehensive Monitoring Team(CMT), modeling and analytics-sub-group.

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.).*

COVID-19 test results history which is associated with participant demographics for assessing participant eligibility (date of birth, student residence location, enrollment status will be viewed).

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

From the public health surveillance testing program at OSU: The following will be recorded with a coded record number: 1)Individuals' day(s)* for the first positive test results (if applicable) 2) most-recent past negative test results' day* (if applicable) The following will be recorded in aggregate: 3) number of participants tested by day* 4) positivity rates by day* The following will be accessed (viewed) but not recorded: 5) Demographic data (to determine participant eligibility: age, residence location, and enrollment status) *days within the academic/financial year (July 1, 2020- May 6, 2021)

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

- □ Grzegorz Rempala
- ■ Mikkel Quam
- ■ Matthew Wascher
- ■ Patrick Schnell
- ■ Joseph Tien
- □ Wasiur Rahman Khuda Bukhsh
- □ Abigail Norris Turner
- ■ Yuhan Pan

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

Uploaded Files

datafile_example_IRB.xlsx

Uploaded by Mikkel Quam on 05/22/2021

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 if a given individual participant was positive for COVID19, when the test was performed, whether the participant has a prior history of testing negative for COVID-19 and when this previous test occurred. To obtain this information, it is necessary to access the public health surveillance testing program's results data which participants authorized sharing with OSU as part of the public health response at the time of testing. Only Co-I Mikkel Quam, along with key personnel Matthew Wascher, Patrick Schnell, Yuhan Pan and Joseph Tien will have access to this PHI, however, the research dataset will be constructed to only contain relevant coded individual participants' testing history.

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

To construct the dataset for retrospective analysis and generate generalizable knowledge from the novel statistical approach, an individual-level history of the transition from negative to positive is needed that can be put into temporal context with aggregated trends within the surveillance population overall (positivity rates, total volume of testing to identify search strength). For the novel statistical modeling inputs, these are minimum necessary information to accomplished the objectives of a) presenting the analysis of OSU COVID-19 testing data in the context of developed methods for peer-review (b) make public computational tools developed by OSU modeling team for other research groups working on COVID-19 or other disease monitoring in the future. The methods for constructing the research datasets intends only to query the minimum necessary portion of the public health surveillance testing records to generate coded datasets for analysis of the serial testing program.

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

The risks of our storing and using coded data that was already collected for this study do not exceed the risk of the COVID testing that was already performed among the same participants to determine their infectivity as part of the OSU COVID surveillance program and swiftly control spread among OSU students and affiliates. The risk of a confidentiality breach will be minimal, given the secured environment where the data is already contained will be where it will remain for any identifiable portions of the analysis. Data explicitly generated for this analysis will be identifiable via a code that can only be linked to participant information through a restricted access data environment, by a limited number of individuals who already require access to such data outside the scope of this research study as part of the pandemic response efforts of the University.

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.*

Any data which may include PHI to be used in this study's analysis was already collected as part of the testing program for public health surveillance. The data/information/records are contained securely within the Research and Analytics Environment-Contact Tracing Data Environment, specifically designed to protect private information of individuals

collected during the COVID-19 response at the University, 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, however only queried to generate the research research datasets in a manner that research in coded and aggregated records. For research reasons including data quality checks and de-duplication of records, it is prudent to retain coded individual identifiers. This will also allow for future checks on the eligibility, should the question arise that would otherwise be impossible were codes not retained. The codex will be stored within the double -authentication secured environment accessible to only those Co-Is and key personnel, who already have access to participant PHI as necessary for Public Health Surveillance and to determine eligibility.

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 three reasons: (Reason 1) Our 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. (Reason 2) Our 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) during intermediate steps that pre-date the analysis and transpire independently (Reason 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.

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 insomuch that it will facilitate the research team's ability to make public for peer review and subsequent use novel methodologies for monitoring transmission of infectious diseases through serial testing, in this case COVID-19. Given that many universities, workplaces, and communities have opted for implementing serial 'test and trace' strategies to control infectious disease transmission in response to this pandemic, novel analytical methodologies as result of this research study can be applied for other managing current and future 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.*

When accessing or analyzing data on individuals' personal health and/or demographic information, there is a risk of breach of confidentiality for any of the participants, whose records are contained within the dataset. There are no new risk, harms, and/or discomforts that is expected as a result of the proposed study considering that the study's analysis is on coded data already collected and archived for public health surveillance. The likelihood of any breach is extremely low, given the restricted access protocols already in place.

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

The security and confidentiality protocols already in place throughout the university's pandemic response and particularly for data access minimized any potential for risk. The further coding and de-identification of datasets used in this analysis serves as an additional protection for any such risk(s).

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

No documents have been added for review.

Research Protocol

IRB-COVID_v3.pdf 05/24/2021

Data collection forms and/or other instruments

datafile_example_IRB.xlsx 05/22/2021

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.