#11112 - RESUMPTION REQUEST: Original Protocol Title Goes Here!

**Submission Type**
New

**Status**
In Progress

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**Basic Information**

*Effective March 15, 2020, to best protect research participants from the effects of COVID-19, in-person research procedures are paused.* The IRB is still reviewing protocols that involve in-person interactions, and you may file those protocols at this time. Approval of this protocol does not constitute approval to conduct in-person research procedures. For that, please also request Resumption of your in-person procedures. *Comprehensive information regarding the pause, resumption of in-person procedures, and resources to support ongoing human subjects research are available on the IRB's COVID-19 Resources website.*

**Resumption of In-Person Research Requests**: If you submitting a request for the resumption of in-person research activities, **aside from the Protocol Title field, please answer these initial questions using the information from the original protocol**. Kuali requires this information to be captured for all submissions, so we are unable to avoid asking for some of this basic project information.

**Principal Investigator**

Vouvalis, Nicole

**Department**

Institutional Review Board

**Protocol Title**

Vouvalis, Nicole
If this is a **request to resume in-person research**, you must write "RESUMPTION REQUEST: [Original Protocol Title]" for the title of your protocol here. Failure to do so will result in your protocol being routed to a different review type.

**RESUMPTION REQUEST: Original Protocol Title Goes Here!**

Please select your anticipated start date for this research, taking care to allow ample time for IRB review.

February 24, 2021

**Is this research externally funded?**

No

**Will this project be used, in part or whole, for a thesis or dissertation project?**

No

**Please indicate what type of review or action you are requesting.** When you make a selection, more information about the type of review will display.

Request to resume in-person research activities

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**Study Personnel**

**USU Personnel**

Please enter all of your USU study personnel to the list below by clicking "Add Info" or "Add a Line." You may double check that they have completed CITI training at this link; unless this is a Non-Human Subjects Research Determination, please do not submit your protocol until all staff are CITI trained.

**You only need to add personnel who will serve as an investigator on this project.**

An **investigator** is an individual who interacts with or intervenes with living people for research purposes; obtains, studies, interprets, or analyzes identifiable private information; obtains informed consent; or interacts with the IRB relating to this study. Individuals assisting with the analysis of de-identified data, for example, would not be investigators under this definition.
### Resuming In-Person Research

**Name**
Vouvalis, Nicole

**Role**
Principal Investigator

**System Role**
Admin

**Full Access**

**USU Personnel Email**

**Department**
Institutional Review Board

**CITI Training Expiration Date**

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**Resources**

This form is used to request the resumption of in-person research activities for a previously-approved protocol. To initiate this process, fill out this submission in its entirety, and then "Submit" using the menu on the right side panel. This resumption request will be reviewed by the Institutional Review Board, which meets every two weeks.
Before submitting this application, please be sure that you have reviewed the following:

- Framework for the Resumption of In-Person Human Subjects Research
- Harvard Global Health Institute's COVID-19 Risk Levels Map for the areas where you will conduct in-person research
- Your original protocol. Any procedures that can be completed remotely or indirectly must be done remotely or indirectly. If this requires an amendment to your original protocol, that amendment should be completed before this resumption request is submitted.
- This supplement to your informed consent process, which must be utilized for in-person activities, absent a granted waiver request.

**New** Two Resumption Tracks

There are two ways to request resumption of in-person research activities. The first is the existing path: moving what can be done remotely to remote procedures, and requesting resumption of low-risk in-person procedures that would not be being performed but for the research project.

The new, second path allows researchers who are creating no new opportunities for exposure to request resumption of their in-person research. The criteria for requests of this nature can be found on page 4 of the Framework for the Resumption of In-Person Human Subjects Research. These are distinct "paths" to resumption and may not be combined, so please make a selection below to submit the appropriate request to the IRB.

Under which Resumption "track" would you like to proceed with this request to resume in-person research procedures?

I am selecting the new resumption track, which permits me to move forward because there are no new exposure threats to participants by continuing in-person research procedures

What is the protocol number for the previously-approved protocol under which you would like to resume in-person activities?

Which of the following activities in your project require direct, face-to-face interaction with research participants?

- Screening
- Informed Consent Process
Data/Specimen Collection Procedures

Please provide a brief explanation for why you are requesting to resume in-person research procedures at this time.
The USU IRB understands that research is important to researchers and to the institution. However, it must balance that institutional priority with considerations for the safety of participants; understanding the need for in-person research procedures amidst the pandemic is helpful in considering the request.

List the location(s) where this in-person research will occur. Be specific, e.g. Adams Elementary School in Logan, Utah.

Describe the relationship between all members of the research team who will carry out the in-person procedures and the setting where the research will occur. For example, a student researcher who is conducting their student teaching in-person in the classroom where the research will occur should be listed in that manner: "Richard Starkey is assigned to the 4th grade classroom at Adams Elementary School, and will be teaching in that role for the remainder of the academic year."

Provide a detailed description of the existing contact that brings the research participants into the setting where you wish to resume in-person procedures. Describe:

1. Precisely what those participants would be doing during their time there regardless of the research;
2. How long the participants would be in that setting; and
3. Who the participants would interact with in that setting absent the research.

Does the location where the research will occur have a reopening or a closure plan specific to COVID-19 that guides its activities during the pandemic?

List the screening activities that are undertaken with the research participants in the organization where the underlying in-person contact will occur. If the organization is not engaging in screening activities, describe screening activities the researchers will implement.

List all Personal Protective Equipment (PPE) that will be utilized in carrying out the in-person research procedures identified above. Each distinct PPE item should be added to the list separately. After identifying the PPE, provide the requested information about each item. Get started by clicking "Add Line" or "Add Info" below.

Informed Consent

Informed consent is a process. Researchers’ responsibility to provide informed consent does not end until the study ends, and sometimes, continues even after that. All participants must be provided any information that could be relevant to their decision to participate, or to continue participating, in any human subjects research project.

Before participants engage with in-person research procedures, they must be given additional information regarding the risks of in-person study participation. A template for documentation is available here. The IRB would consider use of another information sheet, provided the core elements of this document are utilized. Upload a version relevant to your in-person study procedures below.
If your in-person procedures will involve the use of another entity's site or infrastructure, please provide an updated permission to utilize that site dated on or after April 1, 2020. If you are not utilizing another entity’s site or infrastructure, please download, fill in the two required fields, and then upload this document to satisfy the requirement to provide information in this field.

Provide your SOPs for Research here.

To support the contact tracing efforts of Utah's public health officials, you must provide information to participants regarding who they interacted with from your study team, and the approximate date and time they had direct contact with a member of the research team. You can use the COVID-19 Supplemental Study Information documentation for this purpose, if it meets your needs. If you will not come within six feet of a participant for more than ten minutes, you do not need to provide these records.

Initial here to indicate that you understand that you are required to provide these records when coming into close contact (6' or closer) with a participant for 10 or more consecutive minutes.

The primary purpose of an IRB is to minimize risks to participants or others. If COVID-19 cases in Utah begin to drastically increase, the University may move to online-only operations, or the IRB might deem it prudent to pause in-person research procedures once more. In these or other cases, you must be prepared to pause your in-person research procedures. It would be prudent to develop a plan for a stoppage, which might include:

- Ensuring timely communication with your research team
- Ensuring timely communication with your research participants
- Continuation of services via remote means, if possible
- A plan to ensure that a stoppage does not impart harm on research participants or others

Please initial here to indicate that you have or will develop a plan for a potential future stoppage.

In-person research that is approved because the participants are already
interacting with researchers in a location they would already be must follow slowing and stoppage requirements set by that organization, facility, or entity for in-person interactions. Initial here to confirm your commitment to following that facility’s policies, procedures, guidance, and requests regarding COVID-19 mitigation measures.

Before submitting this application, you must ensure that your underlying protocol accurately represents the in-person procedures you wish to complete. This means that any necessary amendments have already been filed and processed by the IRB, such that all in-person procedures that you wish to resume are accurately represented in the underlying protocol. If there is a mismatch between what is submitted here and what is listed in your protocol, this Resumption Request will simply be denied without assignment to a meeting. Initial here to indicate that you have reviewed the underlying protocol and that it is an accurate representation of the in-person procedures you wish to resume.

To facilitate planning efforts, the IRB is permitting these resumption requests to be submitted now, even though the safety indicators for resuming in-person research procedures have not yet been met. You will receive a communication from the IRB on the date that you are permitted to resume your in-person procedures. Initial here to indicate that you are aware that approval of this Resumption Request does not mean that you may begin those procedures, and that you will await clearance from the IRB. This will occur when there is a 14-day sustained downward trend in positivity rates in Utah, as determined using a 7-day rolling average.

Is there anything else you would like to communicate to the IRB regarding your request to resume in-person research procedures for this project? Please bear in mind that the IRB is only permitted to focus on factors that are relevant to the protection of human participants in research.

You may submit your Resumption Request using the "Submit" button on the right hand control panel. Upon receipt, it will be reviewed for completeness and assigned the same review category that applies to your approved protocol. From there, it will be assigned to the next available bi-monthly meeting of the IRB. When it has been assigned to a meeting, a note will be placed in the Admin Notes & Files section of this submission, for your reference.