Basic Information

Resumption of In-Person Research Requests: If you are requesting 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

Department

Protocol Title
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.

USU Aggie Talker Database

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

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

Effective March 15, 2020, the Utah State University Institutional Review Board has temporarily stopped all research procedures that involve in-person interactions. You will be able to file your protocol as though your research will take place under normal university operations. At the end of each section, we will ask for any differences in your research plans while the COVID-19 pandemic is ongoing. Please have your SOPs for Research at hand; they will need to be provided in your protocol submission.

You can learn more about human subjects research and COVID-19 by visiting the USU IRB's COVID-19 Resources page. The Office of Research has a page dedicated to COVID-19 research topics more generally.

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

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; please do not submit your protocol until all staff are CITI trained.
Resuming In-Person Research

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 a task force appointed by the Institutional Review Board, which will meet weekly in August and September.

Resources
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.

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?

Application of Framework Factors to Protocol

The IRB will be assessing eight factors in determining whether it is safe to resume in-person research activities for this project. Those factors are:

1. Proximity, or how proximate participants will be to others, and for how long.
2. Setting, or the location of the research and how that setting mitigates or perpetuates the spread of infectious airborne viruses.
4. **Number of People** in and utilizing the research space.
5. **Age** of research participants.
6. **Health Considerations** related to the targeted participants, such as whether CDC risk criteria for severe illness are present.
7. **Participant Characteristics** that might escalate the risk of sharing or spreading COVID-19 among targeted participants.
8. **Risks and Benefits** of the research.

The items in **blue** (#s 2, 5, and 8) are items the Resumption Task Force will evaluate based on what is **already in your protocol** (so, as a reminder, if you need to amend your protocol, please do so before you submit this request). The items in **purple** (#s 1, 3, and 4) are items you will be asked to address in this Resumption Request. **Bolded black items** (#s 6 and 7) require evaluation of information in the protocol as well as supplemental information that you will be asked to provide here.

There is no single category that will remove your project from resumption consideration. The IRB will examine all of these factors to generate a holistic risk profile for your project, and will make a resumption determination based on that risk profile.

If communities begin to experience high levels of community spread, in-person research procedures should be paused by the research team.

**If the location where you will be conducting in-person research is coded as orange on this map**, you should consider pausing in-person research activities. **If the location where you will be conducting in-person research is coded as red, you must pause your in-person activities.**

**List each county and state where you will conduct in-person procedures under this protocol. Next to the county and state, list the indicators you will utilize to determine whether to continue research in that location.**

**Absent a strong justification to the contrary, in-person research must be preceded by an active screening process to ensure that participants who are at the greatest risk for severe illness, serious long-term health outcomes, or death are excluded from participation.**
Will you be actively screening out participants who are at the greatest risk for severe illness, long-term adverse health outcomes, or death resulting from contracting COVID-19?

Upload your screener(s) here, by selecting "Add Info" or "Add Line" below. The IRB has made several screening tools utilized by different organizations in different settings available on its website, here.

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

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.

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 weekly meeting of the IRB’s task force for resumption of human subjects research.