**Protocol # XX - XXXX**

**COVID-19 Resumption of In-person Research Requirements Template**

In preparation for reinstating in-person human subjects research (HSR), the Virginia Tech Human Research Protection Program (HRPP) and Institutional Review Board (IRB) are providing investigators with the template below, which outlines necessary adjustments for conducting face-to-face interactions with participants during the COVID-19 pandemic. For planning purposes, we have provided a [checklist](https://www.research.vt.edu/content/dam/research_vt_edu/covid-19/sirc/pi-checklist-for-resuming-in-person-research-final.docx) of requirements, consistent with federal guidance about minimizing exposure and reducing risk of contracting COVID-19.

**If you are reinstating a paused in-person study**, the template below must be submitted to HRPP for each study before resuming in-person human subjects research.

If you must alter your protocol or study procedures as a result of COVID-19 (other than elements in this template), please complete a protocol amendment using the typical amendment procedure and submit it when you submit this document.

If your study is with **BRANY IRB** and there are no changes to your protocol beyond what you describe in this form, you do not need to submit anything to BRANY. However, if you need to change study activities in your protocol as a result of COVID-19, please submit an amendment to BRANY using the typical amendment procedures and include this template and the consent addendum.

**If you are proposing a new in-person study**, this template should be completed and uploaded as an “Other/Misc.” study document.

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1. **Statement about scientific validity:** Please outline the effects of COVID-19 and associated prevention measures (e.g., stay-at-home orders, physical distancing) on the **scientific validity** of your research project. Please consider the impact on the validity of study outcomes as well as the independent variables you are collecting.

*Please confirm the continued scientific validity of your research. This is one of the federally mandated criteria for approval.*

***If you do not anticipate that COVID-19 will have any impact on your study****, please state so.*

***Example statement****: We do not anticipate that COVID-19 will have any impact on the validity of our study of stride length of healthy middle-aged adults while wearing backpacks of different weights.*

***If it is possible that COVID-19 will have an impact on your study****, please acknowledge and account for the impacts in the analysis plan. Think about how you might include this information in a journal article.*

***Example statement****: We are midway through our interventional study of loneliness among people with anxiety disorders. Once we resume in-person interactions, we will mark all data points as being pre- or post-COVID-19, and we take this variable into account in our analyses.*

*Enter your scientific validity statement here:*

1. **Statement on specific COVID-19 risks in proposed location and setting.** Please describe the specific risks associated with transmission of COVID-19 while conducting in-person activities in the proposed **location** (e.g., city, state, country) and **setting** (e.g., school, hospital, nursing home).

*Please review the status of the COVID-19 epidemic in the* ***location and setting*** *of your study. We suggest checking the state and local health department’s website for the most current information. How many cases and deaths have been reported? Have they been increasing or decreasing over the previous 2 weeks? Is testing widely available should your team or participants be exposed?*

*Please also review the local COVID-19 public health guidance for the location of your research (e.g., the Virginia Department of Health reports local information) to see whether the type of research you are proposing to begin or resume is allowed. These requirements are changing frequently and vary from location to location. As the PI, you can pause your research at any time, even if HSR is allowed.*

*It is the PI’s responsibility to monitor the location and setting COVID-19 information regularly (e.g., weekly) and to pause the research when warranted. For example, you might need to pause your research if the state reissues a stay-at-home order, the university reverses the decision to reopen research functions and related laboratories, or there is an outbreak where your research is being conducted.*

*This statement should conclude by acknowledging that the PI is responsible for regular monitoring of COVID-19 resurgence and new restrictions in the study location(s) and setting(s), and that the PI will pause the study when warranted. The IRB and HRPP does not need notification when you pause research.*

*Investigators must be aware of risks specific to their study population in the location and setting where the research will take place. Ask facility administrators whether you will be allowed into the facility to conduct research, and under what conditions.*

***For example****, if your research requires conducting an in-person focus group with nursing home residents in Roanoke, you should be aware of the number and trajectory (rising or falling) of COVID-19 cases in Roanoke, as well as the cases and deaths in that facility. You will also want to ensure that your group size is consistent with what is being allowed in the jurisdiction (e.g., <10).*

***Another example****, if you plan to resume research in a Richmond preschool setting, you should be aware of the number and trajectory (rising or falling) of COVID-19 cases in the area as well as in that specific preschool. You will also need to know whether the school is allowing anyone other than students, teachers, and staff to enter the facility.*

*For some studies, this section will be brief (a few sentences), while other studies with higher risk during the pandemic (due to research population, location, or setting), will need a more thorough statement (2-3 paragraphs).*

*Enter your study-specific risk statement here:*

1. **COVID-19 risk mitigation SOP**. All studies must submit a COVID-19 risk mitigation plan that addresses risks in the study setting. For studies conducted in a research laboratory, a single approved plan for the lab is acceptable. If your lab has an approved COVID-19 risk mitigation standard operating procedure (SOP), simply copy and paste it into the box below (or attach as a separate document). For studies conducted elsewhere, a study-specific SOP must be outlined below. Investigators must provide to each participant a **lay language version** of the SOP. The mitigation plan must include a plan for contacting participants who might have been exposed to the virus by a member of the research team or another participant who tested positive within 14 days of their study visit. The contact tracing will be conducted by a health district employee based on the contact tracing log described below. It is the **PI’s responsibility** to start the process by contacting the New River Health District (540-267-8240,) or the appropriate local health authority, about the exposure.

*Please review the* [***Basic Principles for Developing Your Risk Mitigation SOP.***](https://www.research.vt.edu/content/dam/research_vt_edu/covid-19/sirc/basic-principles-for-developing-your-risk-mitigation-sop-final.docx)

*Your risk mitigation plan should be complete, and consider the entire participant experience from arrival, through study procedures, and departure. Consider public health measures such as physical distancing from study staff and other participants; obtaining necessary personal protective equipment for study staff and participants; procedures for donning and doffing masks, gloves, and other protective equipment; and disinfection of surfaces and objects (e.g., pens, clipboards, door handles, sensors, other study equipment).*

*Another way to think about this is to envision the procedures that a small business must prepare to ensure they are following governmental guidance. When you get a haircut, your visit is now carefully orchestrated. This is intended both to reduce risk and to make you comfortable with the steps the shop has taken to reduce risks. Small businesses have begun sending out communications about the steps they are taking to reduce risk and what your experience will look like the next time you visit. This is similar to the lay language version of your risk mitigation SOP. Without this communication, participants might be reluctant to volunteer because they will be unaware of the precautions you are taking and what their visit will entail.*

*SOPs will be longer for studies that involve touch (e.g., placing a cap with electrodes on the head, blood draws) or close contact (e.g., the investigator must stand near the participant to ensure that the participant is using the virtual reality headset correctly). SOPs will also be longer for studies that involve medical equipment that the participant must touch and that will be reused with other participants (e.g., MRI, blood pressure cuff).*

*In addition to the* [***Basic Principles for Developing Your Risk Mitigation SOP***](https://www.research.vt.edu/content/dam/research_vt_edu/covid-19/sirc/basic-principles-for-developing-your-risk-mitigation-sop-final.docx)*, you can also use the most current state and county resources to create your study’s risk mitigation plan.*

*State of Virginia Phase 1 plan:* [*Safer at Home*](https://www.vdh.virginia.gov/coronavirus/frequently-asked-questions/phase-1-safer-at-home/) *(*[*https://www.vdh.virginia.gov/coronavirus/frequently-asked-questions/phase-1-safer-at-home/*](https://www.vdh.virginia.gov/coronavirus/frequently-asked-questions/phase-1-safer-at-home/)*)*

*New River Valley Public Health Task Force*[*: Working Smart, Working Safe: A Guidebook for Reopening your Business in the Age of COVID-19*](https://www.montva.com/docs/default-source/default-document-library/nrv-working-smart-working-safe-resource-guidebook-052020.pdf?sfvrsn=c3306ae1_2) *(*[*https://www.montva.com/docs/default-source/default-document-library/nrv-working-smart-working-safe-resource-guidebook-052020.pdf?sfvrsn=c3306ae1\_2*](https://www.montva.com/docs/default-source/default-document-library/nrv-working-smart-working-safe-resource-guidebook-052020.pdf?sfvrsn=c3306ae1_2)*)*

*Enter your* ***lab SOP or study specific SOP*** *here (or include as a separate document).*

*Enter your* ***lay language*** *version of the SOP here (this is the version that will be provided to participants).*

1. **COVID-19 Risk Addendum to Informed Consent.** Each participant and the investigator must sign and date the Virginia Tech IRB-approved [**COVID-19 Risk Addendum**](https://www.research.vt.edu/content/dam/research_vt_edu/covid-19/sirc/covid-19-consent-addendum.docx). Do not change the text of this form; simply insert the required study information in the header. These addenda shall be stored and retained in the same manner as the original consent forms.

[ ]  *I acknowledge that I will provide the IRB-issued COVID-19 risk addendum to participants and that participants must sign the addendum before they can participate.*

1. **Contact Tracing Log.** Please prepare and maintain a daily **contact tracing log** (paper or electronic) that is distinct from other study rosters, including the scheduling log.
* The PI is responsible for alerting the New River Health District (540-267-8240), or the appropriate local health authority, when a case is reported (originating either from the study staff or a participant). The PI should also email the IRB at IRB@vt.edu indicating that the contact tracing protocol has been initiated (include protocol number or lab name in the email *but no participant details*).
* The daily contact tracing log should be completed by a member of the research team and include participant name and contact information, date of visit, and names of all research personnel and other participants who came into contact with the participant at the visit (information sufficient to conduct bi-directional contact tracing).
* The contact tracing log should be stored securely in a separate location from other study data and information. Location and method of storage should be included in your Risk Mitigation SOP. These should not be stored on or in a desk in a lab or public space that is easily accessible.
* When the PI becomes aware of an exposure to COVID-19 by research staff or participants, a copy of the contact tracing log for all impacted studies must be provided to the New River Health District (or other authorized public health authority) for the purpose of contact tracing.
* The daily contact tracing log must be expunged (deleted or shredded) 60 days after a participant’s last visit.

***Example*** *contact tracing log format and entry:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date** | **Participant Name** | **Email and phone number** | **Study personnel interactions** | **Other participant interactions** |
| June 1, 2020 | Aspen Smith | 540-555-1111Asmith2045@generic\_ email.com | Dakota Jones, Finley Blake, Frankie Neville | Ari Gilbert, Jamie Jones |

[ ]  *I acknowledge that this study will maintain a contact tracing log sufficient to meet the above requirements.*

1. **Changes to Research Materials.** The federal IRB regulations require that any changes to research materials, including recruitment materials, require an amendment, **so if you do not need to alter them, please do not**. If changes are necessary, submit an amendment and adhere to the following guidelines:
* Please ensure that the proposed **reimbursement** and **compensation** amounts reflect expenses incurred as a result of participation and fair compensation for participant time. Participation and completion **incentives** beyond these items should be consistent with pre-COVID-19 incentives to prevent undue influence on a participant’s decision to enroll or continue participating.
* Please refrain from describing the research as “safe.” Instead frame revised wording in terms of having taken steps to reduce risk (e.g., “We have taken steps to reduce risk related to COVID-19 and will provide you with a summary of those steps”).

[ ]  *I acknowledge that my research materials have NOT been altered.*