**Checklist for COVID-19 Resumption of In-Person Research at Virginia Tech**

To minimize risk to the extent possible while the COVID-19 emergency continues, the Virginia Tech IRB will require that all new and reinstated human subjects research (HSR) that can, must be conducted virtually. Before submitting a protocol that includes in-person research, please ensure that all study activities that can be conducted remotely are proposed or modified to be conducted remotely. For amendments, all study activities that were previously approved to be conducted remotely should continue to be conducted remotely.

**The IRB will not require** **researchers to resume in-person research activities**. Each research team must evaluate the risks and benefits and take into consideration the additional precautions that must be taken and decide when to resume in-person HSR. Consider the unique circumstances of your study. Does it involve prolonged proximity with participants, or does it require personal contact between the participant and investigator? Are there sufficient resources to conduct the study (e.g., staff and students) and to mitigate risk (e.g., PPE and disinfecting supplies)? Are you working with a participant population at higher risk of serious complications from a COVID-19 infection? Are any of the study staff at higher risk of serious complications from a COVID-19 infection? These are reasons to consider further delay in resumption of in-person research activities. If you have questions regarding funding implications should you chose not to resume HSR activities, you should contact your project officer at the respective funding agency for guidance.

This checklist provides a high level overview of the requirements. For more detailed information and additional guidance, please see the COVID-19 Resumption of HSR [**Template**](https://www.research.vt.edu/content/dam/research_vt_edu/covid-19/sirc/covid-19-resumption-of-hsr-template.docx)**.**

A Principle Investigator (PI) statement on the effects of COVID-19 and associated prevention measures (e.g., stay-at-home orders, physical distancing) on the **scientific validity** of the research project. Please consider the impact on the validity of the outcomes of interest as well as the independent variables you are collecting.

A PI statement on the **specific risks** associated with transmission of COVID-19 while conducting in-person activities in the proposed **location** (e.g., county, city, state, country) and **setting** (e.g., school, hospital, nursing home). This statement should conclude by acknowledging that the PI is responsible for regular monitoring for COVID-19 resurgence and new restrictions in the study location(s) and setting(s), and that the PI will pause the study when warranted.

All studies must include a standard operating procedure (SOP) that outlines a COVID-19 risk mitigation plan that address the risks in the study setting. A **lay language version** of the SOP must be provided to each participant. The 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. For studies conducted in a research laboratory, a single approved plan for the lab is acceptable. For studies conducted elsewhere, a study-specific plan must be submitted.

Each participant must sign and date the [**COVID-19 risk addendum**](https://www.research.vt.edu/content/dam/research_vt_edu/covid-19/sirc/covid-19-consent-addendum.docx) provided by the IRB. An investigator will also sign the addendum. These addenda shall be stored and retained in the same manner as the original consent forms.

Please prepare and maintain a daily **contact tracing log** (paper or electronic) that is distinct from either the scheduling log or other study rosters. When there is a positive case the contact tracing log should be provided and reported to the New River Health District (540-267-8240).

* 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 two-way 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.
* 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 PI should also send the IRB an [email](mailto:irb@vt.edu) indicating that the contact tracing protocol has been initiated (include protocol number or lab name in email but no participant details).
* The daily contact tracing log must be expunged (deleted or shredded) 60 days after a participant’s last visit.

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”).

As always, HRPP team is available to help facilitate the process, so please do not hesitate to contact us at [irb@vt.edu](mailto:irb@vt.edu) for assistance or questions.