During the COVID-19 pandemic, research resumed at Washington State University under the “staged return to on-site research, scholarship, and creative activities” guidance, which incorporates regulations set forth by public health authorities. The goal of the Exception Request is to approve research, scholarship, or creative activities currently not permitted or clearly addressed under the present “stage” of the guidance via a review process by subject matter experts and college/department/unit leadership on a case-by-case basis. Secondarily, this exception request can be used as a supplemental review if leadership deems activities borderline within the current stage of the guidance. All approval of departures from the guidance must be based on public health authority or medical recommendations and appropriate mitigation/safety measures described. Each Principal Investigator (PI) or research leader must identify specifically any departures from the provisions of the guidance and must state the reasons for each departure in the Exception Request.

Exception Request Process

PIs must submit a draft (complete but without final signatures) Exception Request template below to the Office of Research Assurances Director, Mike Kluzik, via email at mkluzik@wsu.edu. Once the draft is submitted, a preliminary review will be conducted to ensure that the pertinent information is provided. The preliminary review will include, as appropriate, subject matter experts (e.g. EH&S, Office of Research personnel, Facilities Operations, etc.) and any consultation via internal WSU COVID-19 mitigation processes or an external review, depending on the request.

Exception requests will be reviewed along with the portion of the return to research guidance each PI completes for their specific activities (APPENDIX II - CHECKLIST AND WRITTEN PLAN), whether this portion has already been approved or not. Additional supporting documentation, including college/area and department/unit COVID-19 mitigation plans in addition to those already mentioned, should also be provided.

The review will include some or all of the following elements:

1) Evaluating the clear justification of risks and benefits of the research (including those for human subject participants, if applicable);
2) Assessing the mitigation strategies included in the Exception Request are effective, as demonstrated by International, Federal, State, Local, or other pertinent Public Health Authority recommendations;
3) Identifying if additional monitoring or oversight is needed; and
4) Reviewing once more by appropriate oversight committee (e.g., IACUC, IBC, IRB, RSC) for research that has approved protocols, by either the full or a subcommittee (depending on risk), if the exception results in a fundamental change to the research plan (e.g., elements not specifically designed to comply with public health requirements or recommendations). When the research procedures, design and/or outcomes are determined to have fundamentally changed, the exception will be treated as an
amendment to the approved protocol and will receive oversight committee review simultaneous with review of the exception request.

The second step is a return for finalization and official submission to Mike Kluzik, via the PI’s Chair, that includes review/approval from either the Associate Dean for Research/Vice Chancellor for Research or Dean.

The final step, if necessary, is an Exception Request review meeting with the PI or researcher leader, department chair, local campus unit director (as applicable), Associate Dean for Research/Vice Chancellor for Research, Office of Research personnel, and/or other appropriate individuals. The Vice President for Research reserves the right for final approval of Exception Requests.

Statement of Liability

Due to the unprecedented nature of COVID-19 and operating in this era, we have received many questions regarding personal risk and liability in the event of a lawsuit. The University’s policy regarding lawsuits against WSU personnel provides that if a WSU employee is named as a defendant in a lawsuit, the AGO will defend the individual and the state will indemnify them, provided they were acting in good faith in the scope of their WSU duties when the events giving rise to the litigation occurred. There is a request for defense process that must be followed. Please see BPPM 10.15, Lawsuits Against WSU Personnel, for more detailed information about this process.