

Staged Return to Human Subject Research at Washington State University
Version 1.5: April 20, 2021

Purpose and Scope: This document is intended to be supplemental to the WSU [Staged Return to On-Site Research, Scholarship and Creative Activities](#) Stage 3 guidance (04/20/2021) and provides information on safely returning to the conduct of in person research involving human participants. The guidance provided in the original document (03/2020) has not changed, this revised guidance addresses what research may be allowed in the current stage (stage 3) and as future restrictions ease.

The Human Research Protection Program (HRPP) has identified six general categories of research involving human participants in order to determine what research should proceed given current conditions at a research site. The “stages” at an individual research location roughly align with the current phase for a given region in the State of Washington. Effective the date of this revised guidance (April 20, 2021), all WSU locations are moving to stage 3.

To determine if your project can proceed, find the category that is the closest match and the column for the current stage at your location. Categories highlighted in green (in the table below) may proceed without additional consultation. Those highlighted in yellow require additional consultation with the ORA and/or the IRB before proceeding. If you will be working in a location outside of the state of Washington you must follow guidance for that state/region. WSU personnel must comply with WA state requirements regardless of their work location (due to WA State departmental requirements).

If you are having difficulty determining what category your research falls under, what stage/phase the local conditions at your research location correspond with, or developing written plans for returning to conduct research, please review the notes section below or contact the HRPP or Office of Research Assurances.

Human Subject Research Category and Stage (Highlights assume a move to stage 3)

	WSU Return to on-site research plan “Stages”			
	1	2	3	4
Category 1. No in-person Interaction	YES	YES	YES	YES
Category 2. COVID-19 focused research	YES	YES	YES	YES
Category 3: Essential clinical trials	YES	YES	YES	YES
Category 4: Clinical trials (non-Cat 3)	NO	Conditional*	Conditional*	YES
Category 5: Brief interactions	Conditional*	Conditional*	Conditional*	YES
Category 6. All other HS research	NO	NO	Conditional*	YES

***See complete category descriptions below for the conditions that must be met.**

General Categories of Human Subject Research: What is “allowed” in each [Stage](#).

Researchers may request to initiate projects that would not be allowed under the categories/stages described below, but must apply for an exception from the Office of Research Assurances and/or the IRB.

The conduct of all human subject research may be impacted by general directives issued by the County Health Department, State or Federal government or by WSU or local institutions where research is being conducted. Due to the fluidity of this situation it is important to monitor these public health authorities, state agencies and institutional guidance.

For research that is conditionally allowed, vaccination status for both research personnel and participants will be considered as a mitigating factor, especially for those projects that target individuals who may be more susceptible severe disease and hospitalization (e.g. immune compromised individuals, pregnant women).

Some examples of each category of research are provided at the end of this document.

Category 1: No in-person* interactions.

This research is allowed in All Stages (I-IV), provided it complies with WSU and local institutional requirements for safely conducting research.

***For the purposes of this guidance, the WSU Human Subject Protection program (HRPP) defines “in person” research as any research where the researcher and participant are in the same physical location. This term is often used synonymously with “face-to-face”, however the WSU HRPP defines “face-to face” research as occurring in a setting where the researcher and participant are visible to each other (inclusive of Zoom and other web-based applications).**

Category 2: COVID-19 focused research

This research is allowed in All Stages (I-IV), provided it complies with WSU and local institutional requirements for safely conducting research.

Category 3: Clinical trials* involving a therapeutic interventions where either of the following conditions are met:

- COVID-19 focused clinical trials or;
- Clinical trials where:
 - The medical or psychological condition is serious and is having a negative impact on participants and;
 - There is a significant likelihood of direct benefit to individual participants (or potential for negative consequence if discontinued) and;
 - The potential benefit to participants is **equal to or greater than the risk of COVID-19 exposure.

This research is allowed in All Stages (I-IV), provided it complies with WSU and local institutional (e.g. non-WSU) requirements for safely conducting research.

*This is not the same definition as an NIH or FDA clinical trial. For the purpose of this guidance, clinical trial means “research whose purpose is to test ways (e.g. interventions, Implementation strategies) intended to improve detection, diagnosis, treatment, stabilization, or self-management of a health/medical or psychological condition”. This is inclusive of behavioral interventions.

**Risk and benefit may be difficult to quantify in some situations. If it is uncertain that potential benefit is at least equal to (or greater than) the potential risk of exposure, seek IRB guidance or consult with other subject matter experts.

Category 4: Clinical trials, including FDA defined *Phase 1-3 clinical trials, where the criteria under category 3 are not clearly met. This may include trials where the likelihood of a meaningful and direct benefit to individual subjects is uncertain.

This research is allowed in Stage II if the either of the following conditions have been met:

- a [Phase I FDA trial](#) where the therapeutic intervention being evaluated is intended for the treatment of a medical condition that will directly cause severe physical or cognitive impairment and/or death of all participants (see FDA guidance for clarification) or;
- a [Phase II or Phase III FDA clinical trial](#) evaluating a therapeutic intervention for which there is some independent scientific evidence that the intervention is safe and effective in humans and the potential benefit to participants is equal to or greater than the risk of COVID-19 exposure, especially for [populations that may be vulnerable to COVID-19](#).

This research is allowed in Stages III-IV provided that it complies with WSU and local institutional requirements for safely conducting research. In Stage III the potential benefit to participants must be equal to or greater than the risk of COVID-19 exposure, especially for [populations that may be vulnerable to COVID-19](#).

Category 5: Brief (operational definition: no more than 15 minutes) procedure(s) to obtain biospecimens, measurements, and or exams (not including procedures associated with the clinical trials categories defined above). Procedures like drug infusion or imaging (MRI, ultrasound, X-ray, CT scan, PET) are not included in this category as they are not considered “brief”.

This research is allowed in Stage I if the following conditions have been met:

- The focus of the research is COVID-19.
- Procedures are brief in duration (excluding imaging and drug infusion).
- Procedures occur in the context of a clinical care visit and at the same location.

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- Procedures are performed only by a clinical care provider (any medical or behavioral health care provider), interactions with researchers are not allowed in Stage II.
- Procedures are necessary in-person safety monitoring that cannot be eliminated or conducted in an alternative manner.

This research is **allowed in Stage II** if the following conditions have been met:

- Participants are already being seen as part of clinical care.
- Brief procedures can be performed by research staff or a clinical care provider at the same location where the clinical visit is occurring.
- Procedures can be conducted outside of a clinical care setting if the participants were already enrolled.
- The potential benefit to participants must be equal to or greater than the risk of COVID-19 exposure, especially for populations that may be vulnerable to COVID-19.

This research is **allowed in Stages III-IV**, provided that it complies with WSU and local institutional requirements for safely conducting research. In Stage III the potential benefit to participants must be equal to or greater than the risk of COVID-19 exposure, especially for populations that may be vulnerable to COVID-19.

Category 6: All other research (including clinical trials that do not involve a therapeutic intervention).

This research is **allowed in Stages III-IV**, provided that it complies with WSU and local institutional requirements for safely conducting research. In Stage III the potential benefit to participants must be equal to or greater than the risk of COVID-19 exposure, especially for populations that may be vulnerable to COVID-19.

This document will be reviewed and revised as needed and will align with any updated guidance (e.g. CDC guidance, WA governors safe start plan).

Supplemental information: Important notes about this guidance

- No guidance will be able to address all research situations/conditions, as such, please view this as general guidance for the conduct of human subject research. Direct any project specific questions to the [Human Research Protection Program](#).
- Research conducted outside of the State of Washington must comply with local requirements. If local requirements exceed WSU, State or Federal requirements, they must be followed. WSU employees must, at a minimum, follow [Human Resource Services](#) (HRS) and Environmental Health and Safety (EH&S) guidance to ensure their safety regardless of location. Non-WSU employees (e.g., those subcontracted to WSU) should follow local requirements unless otherwise required by law and/or contract.
- Some projects that would have been allowed in a given “Stage” have not able to proceed due to the impact of other directives (e.g. [Suspension of personal protective equipment \(PPE\) usage for research, replaced](#) on June 5, 2020, and the limitation of certain research activities under the [Stay Home, Stay Healthy directive](#)). For this reason, it is important to monitor Federal, State and Local directives (via the [WSU Updates: Coronavirus COVID-19](#) web page) and update research planning accordingly.
- **Key Concept to Human Subject Research:** Potential COVID-19 exposure is a new “risk of daily life” for all individuals who go to public places. Therefore, it is not always a risk specific to (caused by) participation in human subject research.
 - Generally, assessment of risk and risk benefit analysis due to “daily” COVID-19 exposure does not require review and approval by the IRB, but must be approved by the WSU process summarized briefly in section 6.c and on the [WSU Research COVID-19 web page](#).
 - Researchers may not always know (or be able to inquire) if their participants are at higher risk in studies in which vulnerable populations with clearly defined health problems are not the focus of the research. In situations of undefined risk, consider implementing additional precautions (see 6.b.iii) or providing simple [information sheets](#) to research participants.
- COVID-19 exposure is only a new or elevated risk, specific to a research project, when participation in the research project causes the probability of exposure to be elevated above that encountered in daily life.
 - Examples may include research that focuses on individuals **known** to be more vulnerable to COVID-19 infection than young, healthy individuals.
 - Where COVID-19 “risk” or “populations vulnerable to COVID-19” is mentioned in this document it is meant as an abbreviated way of stating “risk of developing COVID-19 illness” or is referring to CDC guidance: “[People Who Are at Higher Risk for Severe Illness](#)”. At risk sub-groups of the population include the elderly, individuals with certain co-morbidities or

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- immunocompromised individuals, who might otherwise limit their public exposure if they were not participating in research.
- **When a researcher wishes to initiate or resume this type of research in advance of the stage in which it would be allowable by default (consistent with [Federal](#), [State](#), [County](#) and [WSU HRS /Office of Research](#) guidance), they must submit an amendment or new protocol to the IRB that includes a detailed plan for mitigation/minimization of this risk to participants so that the IRB can re-evaluate the risk-benefit ratio. IRB approval must be obtained before the research may commence.**
 - All activities, including human subject research, require thoughtful planning to mitigate the risk of COVID-19 transmission to employees and participants, who may subsequently transmit the disease to others.
 - All individuals returning to WSU locations (e.g., campuses, labs, offices etc.) must comply with all applicable requirements:
 - Employees returning to WSU work locations must comply with [HRS return to work requirements](#). To access required training for Faculty and Staff click on “return to work requirements” and sign in to the online learning system.
 - When available, information related to any testing or contact tracing requirements will be found at: [WSU Coronavirus COVID-19](#).
 - Students can complete COVID-19 training via [EH&S](#) and [Blackboard](#).
 - Review the Guidelines for return to on-site research activities (Appendix I of the [staged return](#) plan).
 - Complete a written plan and checklist (Appendix II of the staged return plan) that is required for return to on-site research, with the exception of research that is conducted solely by a single individual in a private office (checklist approval may not be required in these instances).
 - When required, certification of the checklist and plan must be obtained. For a summary of the approval process, see section 6.c.
 - The written plan for a human subject research project may reference, but does not need to restate, the general requirements listed above.
 - For human subject research, planning must include two key elements: mitigation of risk to researchers (A. faculty and staff, B. students, and C. volunteer staff) and mitigation of risk to research participants.
 - While these elements will be part of a complete plan, they must be addressed separately due to the different nature of individual affiliations to WSU.
 - As such, it is important to follow WSU guidance, [HRS guidance](#) and EH&S guidance in the development of the mitigation strategies for employees, students and volunteers, and to follow Federal, State and Local public health guidance (links provided in section 6.b above) in the development of all mitigation.

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- A description of recommended mitigation strategies, such as physical distancing, [cleaning and disinfecting](#) can be found at [CDC.gov](#) and may include (but are not limited to) the following:
 - Allow for physical distancing between researchers and participants. Consider marking floors to indicate the appropriate distance to maintain from any commonly used equipment.
 - Limit the number of research participants present at any given time.
 - Preferably participants would not be in the same physical location at the same time and would not use common research equipment unless effective cleaning and disinfection is performed between uses.
 - Space out appointments with research participants to allow time for [effective cleaning and disinfection](#) of the research space and equipment in between.
 - For procedures that normally require interaction between the researcher and participant (e.g. blood collection, biometric measurements), where physical distancing recommendations cannot be adhered to, consider if alternative approaches or altering methods could help minimize the time that the researcher and participant are in close proximity.
 - Note that these types of procedures may not be allowed outside of clinical care settings during some stages (see stage definitions below).
 - For the purpose of this guidance, “[clinical care settings](#)” is inclusive of hospitals, clinics and other locations (including provision of in-home clinical care) where medical or behavioral care is provided. See: [CDC Clinical Care Guidance](#) for more information.
 - Implement procedures, consistent with WSU and State guidance, for assessing if a participant may be ill, and require that participants who are ill reschedule their appointments (with the exception of COVID-19 research where participants are expected to be ill).
 - Consider that some participants may be especially vulnerable to COVID-19. Consider additional procedures for assessing and mitigating risks to such vulnerable individuals, especially if they are the focus of the research.
 - If there are concerns about the physical location where research is to be conducted (e.g. adequate ventilation), consult with Facilities Services and/or [EH&S](#).
- When required (see exceptions in section 6.a.iv.1), the return to on-site research plan must be approved before commencing research.
 - When required (see 6.a.iv.1 for exceptions), PIs develop a return to onsite research plan, complete the checklist and confirm that all

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- researchers have completed training and other general requirements for returning to the workplace.
- The plan is submitted to the local area director (e.g. Chair, ADR, VCR, or Dean) for approval. See the WSU “staged return to research plan” or contact your department if you are uncertain who your local area director is.
 - If researchers or local area directors have questions about developing or approving a plan, they should consult with the implementation work group or review the most recent guidance provided by the [Office of Research](#).
- COVID-19 pandemic conditions are fluid and may vary by location/campus, therefore it is important to follow your [local county guidance](#) and local institutional policies (e.g. when conducting field research, research associated with WSU extension, research in a clinical or other health care or community setting).
 - Each written plan should account for the possibility of moving between stages when a change (in either direction) occurs in a county or region “phase. Each plan should also address as well as possible [shortages](#) of [personal protective equipment \(PPE\)](#) or other supplies, and staff absences due to illness.
 - PIs should monitor their written plans to ensure they are effective and/or account for a change in current circumstances and revise/update their written plans when appropriate to ensure they effectively mitigate risks of adverse outcomes related to COVID-19 and the spread of SARS-CoV-2.

Examples of WSU research by category:

Category 1 Example: The research involves the conduct of in-person interviews or the use of questionnaires that have been moved to face-to-face via zoom and/or electronic documents due to COVID-19. These interviews may be conducted via Zoom in all stages (no risk of COVID-19 transmission) or may be conducted in-person in phases III-IV provided all other requirements are met. In some cases, the researcher may wish to return to in person settings to ensure that individuals without internet access are able to participate (ethical principle of Justice).

Category 2 Example: The research involves determining the risk of transmission of COVID-19 via breastmilk. The samples are taken in a clinical care setting.

Category 3 Example: The research is a controlled clinical trial that will test low doses of a drug on moderately ill COVID-19 patients who have none of the risk factors (contraindications) that would prevent the prescription of that drug.

Category 4 Example: The research is a clinical trial that involves a behavioral intervention meant to influence the impacts of alcoholism in a population where this condition leads to death at a very high rate when compared to the general population.

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Category 5 Example: The research involves genetic testing for factors that might predispose an individual to the condition under study. The tests are accomplished using blood samples or saliva samples that can be taken via brief interaction with participants.

Category 6 Example: The research involves more than brief interaction with participants, up to and including overnight stays in a research facility.