Key elements of the "Staged Return to Human Subject Research at Washington State University" guidance document.

1. The attached guidance for a "Staged Return to Human Subject Research at Washington State University" (hereafter referred to as "guidance"), is based on the WSU Guidance (version 1.1): "Staged return to on-site research, scholarship and creative activities". **WSU "Stages" follow, but are not the same as, WA safe start "Phases".**
2. The guidance is dependent upon, and requires compliance with, all applicable guidance including: Federal guidance (e.g. CDC), State guidance and directives (e.g. WA "Safe Start Plan", WA State COVID-19 Risk Assessment Dashboard, Washington State Labor and Industries), Local public health authority requirements (e.g. Whitman County Public Health) and WSU Guidance and Policy (WSU HRS Return to Work Plan and WSU Environmental Health and Safety).
3. The guidance has been developed to be generally applicable to all WSU campuses and research locations (inclusive of other states and international research) and requires WSU researchers to comply with local requirements. If local requirements exceed WSU campus requirements, they must be followed, otherwise WSU employees are expected to follow WSU policy.
4. The guidance addresses potential exposure to COVID-19 as a new risk of daily life and does not require IRB review of measures implemented to protect the health of employees, research participants or members of the public when those activities are required in all situations (are not exclusive to the conduct of research).
5. IRB approval is required whenever implementation of a change to the research would potentially increase the risk to research participants or others (or alter the risk-benefit ratio).
6. This guidance was developed by a working group of subject matter experts representing: The WSU Office of the Attorney General, Human Resource Services, Human Research Protection Program, and Biosafety Officer as well as Associate deans and Vice Chancellors for Research and active research Faculty.
7. The guidance is consistent with other research-intensive academic institutions.
8. The general categories of research described in the guidance (shown below) are consistent with, and expand upon, those currently in use by the University of Washington.
9. Guidance was shared with and vetted by the Research COVID-19 Work Group as well as the WSU RMAG. The current version reflects their recommendations.

Categories of Human Subject Research by Stage. WSU Return to on-site research plan "Stages"

	1	2	3	4
Category 1. No in-person Interaction: Approximately 40+% of research has been adapted to continue throughout the pandemic and does not require in person interactions.	YES	YES	YES	YES
Category 2. COVID-19 focused research: Categories 2-4 represent no more than 5% of WSU human subject research but this type of research is rapidly increasing.	YES	YES	YES	YES
Category 3: Essential clinical trials: Includes some FDA trials	YES	YES	YES	YES
Category 4: Clinical trials that do not meet category 3 criteria	NO	Conditional	Conditional	YES
Category 5: Brief interactions: Research that requires some interaction with participants, like blood draws or measurements, represents more than 30% of WSU research.	Conditional	Conditional	Conditional	YES
Category 6. All other HS research that requires in person interactions but does not meet the criteria for any other category, (procedures are not brief) or where the project intentionally involves populations that may be vulnerable to COVID-19. Less than 25% of WSU projects.	NO	NO	Conditional	YES

Staged Return to Human Subject Research at Washington State University
Version 1.2: June 16, 2020

Purpose and Scope: Washington State University (WSU) planning and guidance, including the "Staged Return to On-Site Research, Scholarship, and Creative Activities", has been developed to accompany the 4 phased Washington "safe start plan". The Staged Return to Human Subject Research document is intended to provide guidance for restarting human subject research and applies to protocols with current approval by the Institutional Review Board (IRB). The process for starting new human subject research protocols will be similar and guidance for moving between stages provided below will apply to new protocols.

This guidance addresses moving between the stages described in the WSU Staged return to research plan and indicates what types of human subject research are allowable in each stage. WSU stages follow, but are not the same as, county/state phases. For human subject research in Washington, the current phase of the county in which it takes place may vary by campus/location/county. Check with your local area director or county health department to confirm the current phase for your campus/location. See also, WA State COVID-19 – Risk assessment dashboard.

1. 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.

2. 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.

3. Note that some projects that would have been allowed in a given "Stage" were 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.

4. **Key Concept to Human Subject Research**: Potential COVID-19 exposure is now a "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.
    a. 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 below and on the WSU Research COVID-19 web page.
    b. 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.

5. 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.
   a. Examples may include research that focuses on individuals **known** to be more vulnerable to COVID-19 than young, healthy individuals.
   b. 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 immunocompromised individuals, who might otherwise limit their public exposure if they were not participating in research.
   c. 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.

6. 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.
   a. All individuals returning to WSU locations (e.g., campuses, labs, offices etc.) must comply with all applicable requirements:
      i. 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.
      ii. When available, information related to any testing or contact tracing requirements will be found at: WSU Coronavirus COVID-19.
      iii. Students can complete COVID-19 training via EH&S and Blackboard.
      iv. Review the Guidelines for return to on-site research activities (Appendix I of the staged return plan).
         1. 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).
         2. When required, certification of the checklist and plan must be obtained. For a summary of the approval process, see section 6.c.

v. The written plan for a human subject research project may reference, but does not need to restate, the general requirements listed above.

b. 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.
   i. 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.
   ii. 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.
   iii. 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:
      1. Allow for physical distancing between researchers and participants. Consider marking floors to indicate the appropriate distance to maintain from any commonly used equipment.
      2. Limit the number of research participants present at any given time.
         a. 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.
         b. Space out appointments with research participants to allow time for effective cleaning and disinfection of the research space and equipment in between.
      3. 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.
         a. Note that these types of procedures may not be allowed outside of clinical care settings during some stages (see stage definitions below).
         b. 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.
      4. 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).
5. 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.
6. 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.

c. When required (see exceptions in section 6.a.iv.1), the return to on-site research plan must be approved before commencing research.
    i. When required (see 6.a.iv.1 for exceptions), PIs develop a return to onsite research plan, complete the checklist and confirm that all researchers have completed training and other general requirements for returning to the workplace.
    ii. 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.
    iii. 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.
d. We all recognize that the COVID-19 situation is 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).
e. Each written plan should account for the possibility of moving between stages when a change (in either direction) occurs in a county's "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.
f. 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.

General Categories of Human Subject Research: What is "allowed" in each Stage.

- **Research that is continuing, and is allowed to continue, as approved by the IRB, with the sole change being implementation of general COVID-19 mitigation strategies required by WSU, the County Health Department, State or Federal Government do not need to obtain additional IRB approval. These changes are not specific to the conduct of human subject research, they are public health measures intended to mitigate a risk of daily life.**

- **Researchers may request to implement research procedures that would not be allowed under the categories/stages described below, but these research procedures must first be approved by 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.**

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 intervention including the following:

- 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: it is either 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 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.

- 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.
- The bullets listed above apply only to participants who were already enrolled and participating prior to March 23, 2020.

This research **is allowed in Stage II** if:

- 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).

Categories of Human Subject Research by Stage.

	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 for more detail.