

Resuming Some Human Subjects Research

Karen Moe, Human Subjects Division

SOM Research Town Hall

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Topics

1. Expansion of allowed human subjects research
2. Mandatory requirements for all in-person human subjects research

Context and Decision Process

March 23. Temporary halt implemented for most research involving in-person interactions.

Rationale. Which halted research to now allow?

- Consistency with state and UW-wide relaxation
- Consultation with public health experts
- Consultation with IRB Chairs
- Consultation with UW research leadership
- Consideration of risks/benefits to participants

Keep in mind

- This first step is somewhat conservative.
- Additional research will be allowed in the future as appropriate.
- Changing conditions may require a return to previous limitations & restrictions.



Where to find the information

Available at the end of the day today

- New subpage of HSD COVID-19 webpage
- New CHECKLIST
- Revisions to general HSD COVID webpage

Formal announcements tomorrow morning

- Announcements to Vice/Associate Deans for Research
- HSD eNewsletter
- MRAM announcement
- Research Advisory Board members

Summary: Expansion of allowable research

1. Clinical trials
2. Sole in-person procedure(s) are for brief
 - Specimen collection
 - Physical exam
 - Physical measurement

Newly-allowed Clinical Trials

Research whose purpose is to test ways to improve diagnosis, treatment, stabilization, or self-management of a medical or psychological condition.

Phase 2 and 3 trials evaluating a therapeutic intervention

Phase 1 studies evaluating a therapeutic intervention and:

- The medical condition will inevitably & directly cause devastating physical or cognitive impairment and/or death of all participants
- Other interventions do not exist or have significant serious side effects or significantly limited effectiveness

ALL clinical trials must meet these requirements:

- Specific locations. UW & Seattle Childrens Translational Research Unit (TRU); UW Medicine, Seattle Childrens, or SCCA clinical facility or setting. Consult HSD about others.
- Permission from location. Research must be allowed by the location. See communications from UW Medicine & SOM leadership, and/or clinic manager.
- HSD and generic UW requirements. Described in the new HSD Checklist.

Newly allowed sole in-person procedure(s):
Brief specimen collection, physical exam or measurement

Who can perform the procedures

The procedure(s) can now be performed by study staff or any clinical care provider, at the specific clinical care location where the clinical visit is occurring

Already-enrolled participants in ongoing longitudinal studies

The procedures can be performed solely for research and outside of a clinical facility but only for participants who had already completed at least one study visit prior to March 23

Research Location

The changes apply to all locations, with the following considerations

In general, must ensure that the research is allowed at the location.

UW Medicine clinical facilities and settings

- They have their own policies, restrictions and requirements
- Must use an approved facility/setting (e.g., TRU) or obtain permission

Outside of Washington State

- Research allowable in Washington State per these guidelines may not be appropriate in other locations. UW researchers should consider the local public health and pandemic context as well as local requirements. If local requirements are more relaxed than UW requirements, the UW requirements must nonetheless be followed.

UW research reviewed by an External IRB

External IRB = a local, non-commercial IRB (e.g., Hutch, SC)

Follow the requirements and policies of the External IRB, in addition to the generic UW requirements (not the HSD requirements).

External IRB = any other IRB

Follow the HSD and generic UW requirements.

UW as Single IRB

Non-UW sites being reviewed by the UW IRB for a collaborative or multi-site study: Follow the policies and requirements of their own institutions.

Mandatory Requirements

HSD Checklist for Human Subjects Research During the COVID Pandemic

- Describes all HSD requirements plus campus-wide requirements
- Intended as a helpful tool. Do not attach to your IRB application.

Many campus-wide requirements are very recent. Check this frequently!

The CHECKLIST will be kept up to date as requirements change.

Questions?

hsdinfo@uw.edu