

# Resuming Some Human Subjects Research: Clarifications

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# Context

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

**May 22.** Some halted research allowed to resume or begin

- Some clinical trials
- Some research for which sole-in-person procedure(s) are for brief:
  - Specimen collection
  - Physical exam
  - Physical measurement

# HSD webpage describes the categories of allowed research

<https://www.washington.edu/research/hsd/covid-19/resuming-some-human-subjects-research/>



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Resuming Some Human Subjects Research

## Resuming Some Human Subjects Research

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**Effective May 22, some temporarily-halted UW human subjects research may resume and or begin.** The [tables below](#) describe the types of research that can now occur.

### Summary of May 22 changes

1. The description of already-allowable research has been re-worded to fit into the new categories described below. This is intended to improve usability and make it easier to incorporate future changes.
2. Expansion of allowable clinical trials.
3. Expansion of studies whose only in-person procedure is brief and for the purpose of obtaining a specimen, measurement, or specific physical exam.

# How to use the information about what is allowed?

*How do the categories relate to each other?*

Think of the Categories as a **decision tree**

## Category 1?

Yes: Resume or begin your research. No need to look at other categories.

No: Look at Category 2

## Category 2?

Yes: Resume or begin your research. No need to look at other categories.

No: Look at Category 3

## Category 3?

Yes: Resume or begin your research. No need to look at other categories.

No: Look at Category 4

## Category 4?

Yes: Resume or begin your research. No need to look at other categories.

No: Your research cannot resume or begin.

## Category 3: What is a “clinical trial”?

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

NOT the same as the NIH definition

# Which clinical trials are now allowed?

## All of these criteria must be met

- **Delivery & investigation of a therapeutic intervention**
- **Phase 2 or 3**
  - Means there is some independent scientific evidence in humans that the intervention works and is safe
  - Some very specific types of Phase 1 trials are also allowed
- **Procedures conducted in one of these clinical facilities**
  - UW Medicine
  - Seattle Childrens
  - SCCA
  - Consult with HSD about others [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu)
- **Permission of the clinical facility**

# What about cancer trials reviewed by the Hutch IRB?

**ALL cancer trials reviewed by the Hutch IRB can be resumed/started if the relevant Disease Group says it is OK**

- Per memo from Dr. Appelbaum, April 21<sup>st</sup>
- Contact the Clinical Research Support office or the head of your Disease Group

**Must comply with generic UW requirements for resuming research:**

Checklist for Developing a Return to In-person Research Plan

<https://www.washington.edu/research/or/guidance-for-returning-to-in-person-research/>

# Allowable in-person procedures?

**Category 2 (COVID-related research)**

**Category 3 (allowed clinical trials)**

ALL necessary in-person procedures are allowed

But procedures should be done remotely whenever possible

## Examples

- Recruiting & screening (for parts that can't be done remotely)
- Imaging
- Drug infusions
- Repeated blood sampling from IV catheter during visit



# Category 4: Specific types of in-person procedures

## All of these criteria must be met

- **Type** of in-person procedure is specimen collection, physical measurement, physical exam (does not include imaging)
- **Duration** is brief
- **When:** only as part of a clinical visit (not a visit for just research)  
Exception: Can be conducted solely for research but only for longitudinal studies started prior to COVID and for which the participant had already had at least one study visit

*This is intended to be a narrowly-defined category*

# Mandatory Requirements for all in-person Research

## **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?

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