

From: dellmed.research.list-request@utlists.utexas.edu on behalf of [Dell Med Office of Research](#)
To: dellmed.research.list@utlists.utexas.edu
Subject: [dellmed.research.list] Human Subjects/Laboratory Research - approval process for 9/23 changes
Date: Monday, September 14, 2020 11:53:36 AM

COVID-19 UPDATE

OFFICIAL COMMUNICATION FROM THE OFFICE OF RESEARCH

As you have likely seen last week from the UT VPR (email below), we are proceeding with resuming some human subjects research, in addition to increasing capacity of laboratory research, up to 50%.

HUMAN SUBJECTS RESEARCH

Please review the [VPR guidelines](#) and complete [this new application form](#) by Friday, September 18, to enable review and approval of your human subjects projects. As the VPR has created additional tracking and reporting criteria, we are asking that you submit your approval request even for those projects previously submitted. You may have also seen [the announcement from Seton](#) about the ending of their research pause.

LABORATORY RESEARCH

The VPR guidelines allow for up to 50% capacity starting 9/23 for laboratory research, pending approval. We will be sending out an updated survey early next week for those that want to increase the number of personnel in either of the two shifts.

We will plan to review your submissions and provide an update by September 23.

Thank you for your understanding and adherence to guidelines, in addition to maintaining safety protocols, so that we can keep everyone as safe as possible while increasing research activity.

Sincerely,

Dell Med Office of Research

From: The Office of the Vice President for Research [mailto:do-not-reply@utlists.utexas.edu]
Sent: Friday, September 11, 2020 12:03 PM
To: cdw3249@eid.utexas.edu
Subject: Resuming Human Subjects Research and Workforce Density Updates



This message has been distributed to all UT employees with Principal Investigator (PI) status, as well as all UT graduate students and postdocs.

Dear PI Colleagues, Graduate Students, and Postdocs,

In my [email](#) to you at the start of the semester, I mentioned that both the Research Working Group and Health Working Group were developing a plan to allow some forms of human subjects research to resume on campus. I'm pleased to let you know that we now have an IRB-endorsed plan in place. Beginning **Wednesday, September 23**, principal investigators may apply for approval to resume some projects paused due to the COVID-19 pandemic. I appreciate everyone's patience as our teams built a process to support your work while thinking very carefully with UT's health experts about the safety of all involved in this kind of research. The full plan, with procedures, guidelines, and required forms, can be found on our new [Human Subjects Research Restart page](#). Please note that if your team has been conducting projects remotely/virtually with study participants, those may proceed without any additional approvals.

This memo will be most relevant to those of you who conduct human subjects research and wish to resume that research in person, but all researchers should review the changes to the workforce density limit that I outline below.

Overview

The plan's overarching goal is to keep everyone as safe as possible. All efforts to resume human subjects research will follow the principles outlined in our overall [Research Restart plan](#) while also adhering to new requirements, such as obtaining informed consent, performing COVID-19 screenings, and evaluating the potential benefits of each study relative to the risk of COVID-19 transmission.

Resuming human subjects research also necessarily affects our workforce density limit because new and additional researchers will need to return to campus. Therefore, **we are increasing our workforce density cap from 30-40% to 50%, also effective September 23**. This increase in workforce density applies for all on-campus research allowed under Research Level 3, not only human subjects research. Please note, however, that all other Research Level 3 policies remain in place, including

strict adherence to shift and cohort schedules.

One key reason why we are able to resume human subjects research, as well as increase our workforce density limit, is because local COVID-19 positivity rates have dropped below 5%. While cases have risen within the UT community corresponding to the start of fall classes, the overall numbers in [Travis County have dropped substantially](#). This is encouraging, but we can't become complacent. University leadership will continue watching these trends carefully, and if conditions change, we will respond accordingly.

Important Things to Know About Human Subjects Research

There are three requirements that must be in place before you may reactivate or begin face-to-face interactions with study participants:

- You must have approval from your college, school, or unit, typically through your [associate dean for research](#) (ADR).
- You must have Institutional Review Board (IRB) approval for the activities you will conduct. If your study procedures are already IRB-approved, no further notification to the IRB is necessary for reactivation.
- The study must fall within the scope of the currently approved Human Subjects Research Restart Tiers (Tiers A, B, and C), which you can find outlined and explained [here](#), in full. This document also covers important COVID-19 procedures all researchers must follow along with guidelines so you can evaluate the risk of COVID-19 transmission and the potential benefits the study will have on individual participants. This risk-to-benefit matrix is what allows you to see which Human Subjects Research Restart Tier your study is assigned to and, therefore, if it's allowable at this time.

Additionally, we've made two forms available that you will need once you receive ADR and IRB approval to resume your work:

1. A [Participant Consent Form \(COVID-19 Addendum\)](#), available in English and Spanish, which should be used in addition to other IRB-approved consent forms
2. A [COVID-19 Symptom Pre-Screening Form](#), available in English and Spanish

If you have questions, please see our [human subjects research FAQs](#) or talk with your ADR.

[Human Subjects Research Restart](#)

Undergraduate On-Campus Research

In my [August 28 email](#), I also let you know that the Fall 2020 Planning Executive Committee was considering a process for resuming limited undergraduate on-campus research this semester. The committee is still monitoring campus conditions closely and will make a decision early next week after reviewing COVID-19 case data. It's important to see the effects from Labor Day weekend, if any, and if those resulted in a substantial increase in cases within our community. I will follow up with you next week and provide more detail at that time.

Volunteer for Proactive Community Testing

And as always, please consider volunteering for proactive community testing. As I've said before, this is one of the critical pieces that helps the university monitor the prevalence of COVID-19 on campus. **This is especially important if you are returning to campus for the first time.** You can be tested every 14 days, and I encourage you and your teams — faculty, staff, and students — to make it a regular habit. Tests are quick, painless, incur no out-of-pocket fee, and results are available within 24 hours. [For more information, to make an appointment, and to see today's testing site location, visit the Healthy Horns website.](#)

Sincerely,

Alison Preston Signature



Alison R. Preston, Ph.D.
Interim Vice President for Research

This communication is from Principal Investigators – Official.
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