

How do I get Essential Research Functions Approved?

Conducting limited on-campus research functions during the pandemic:

A guide for PIs and Chairs

March 29, 2020



Stanford | Vice Provost and
Dean of Research

Essential Research Functions

At this time, no researcher should be physically present in campus laboratories or research spaces except to conduct approved Essential Research Functions, [defined in a March 17 memo as:](#)

- maintenance required to preserve laboratory viability;
- certain clinical research per SOM [Guidance for Clinical Trials and Clinical Research](#); and
- COVID-19 research that has the clear potential to reduce the spread of COVID-19 or its impact on human health.

Essential Research Functions

All key personnel who wish to engage in on-campus research activities **must first get approval.**

- For maintenance functions, follow the EH&S Essential Research SmartSheets Process on slide 5.
- For COVID-19 research in on-campus labs, follow the EH&S Essential Research SmartSheets Process on slide 6.
- For Clinical research, first contact your Department Chair, then contact the COVID-19 Clinical Research Review Panel on slide 7.

Student and Postdoctoral Researchers

- No student or postdoctoral scholar should be required to go into the lab.
- Students with concerns should contact their department chair, student services staff, or the associate dean for student affairs in their School.
- PIs with concerns about the availability of personnel to carry out any lab-specific critical procedures should consult with their department chair or building manager.

Approval to Conduct Maintenance Required to Preserve Lab Viability

1. **The PI (or their designee)** submits proposed activities through Essential Research SmartSheets.
2. **The Department Chair or Institute Director** who has cognizant authority over the lab space, together with the DFO/DFA (or local equivalent), reviews the Essential Research SmartSheets for each PI proposing *critical* activities and confirms that
 - the proposed activities meet the definition of Essential Research Functions (slide 2),
 - the identified personnel have received appropriate social distancing and hygiene guidance, and
 - the department can accommodate these activities at this time.
3. **School and Dean of Research** review the list of approved activities for each department. *DoR Essential Research Functions Review Committee*: Kam Moler, Ruth O'Hara, Tim Stearns.

Approval to Conduct COVID-19 Research in Labs

Do not conduct on-campus research until all 3 steps are complete. We will try to expedite approval.

1. The PI

- ensures that any other approvals and training that normally need to be in place are in place (IRB, APB, OGC, ICO, etc.);
- submits proposed activities through Essential Research SmartSheets; &
- sends details about their projects to the DoR COVID-19 Lab Research Review Committee, care of geerke@Stanford.edu, and to their Department, Institute, and/or School.

2. The Department Chair or Institute Director who has cognizant authority over the lab space, together with the DFO/DFA (or local equivalent), reviews the Essential Research SmartSheets for each PI proposing critical COVID-19 research activities and confirms that

- the identified personnel have received appropriate social distancing and hygiene guidance, and
- the department can accommodate these activities at this time.

3. The Cognizant School and the DoR COVID-19 Lab Research Review Committee (Kam Moler, Ruth O'Hara, Tim Stearns, Chaitan Khosla, Rhiju Das, and Catherine Blish) review the projects, reaching out for additional details as needed, and notifying PIs of approval.

Approval for Clinical Research, Including COVID-19

- **Non-Essential Clinical Research**
 - Postpone all non-essential, in-person patient or human subjects visits until further notice.
 - Postpone all new studies that have not yet started.
 - Proceed with research you can conduct virtually.
- **Clinical Research:** Continue with in-person visits in cases where
 - ongoing treatment studies provide essential therapeutic support for our patients.
 - cessation of the treatment could negatively impact patient outcomes.
 - failure to conduct laboratory measures or to make in-person observations in clinical research could compromise the safety of vulnerable patients or populations.
- **Determining Which Treatment Trials or Clinical Observation Studies that Require In-Person Visits Can Continue:** Consult with your Institute Director or your Department Chair.
- **Approval for COVID-19 Clinical Studies:** First, contact your Departmental Chair or Institute Director for their approval. Then contact the COVID-19 Clinical Research Review Panel (via Pooneh.Fouladi@Stanford.edu) chaired by Drs. Ken Mahaffey and Upinder Singh, who will review the proposals and adjudicate priorities.
- Take all necessary safety precautions outlined on the EH&S website for all in-person visits.

Other Approvals

Other approvals that may also be needed include:

- APB (Administrative Panel on Biosafety)
 - Biological agents classified as Biosafety Level 2 (BSL-2) or above
 - rDNA classified as non-exempt by the National Institutes of Health (NIH)
- IRB +/-SCRO (Institutional Review Board, Stem Cell Research Oversight)
 - research involving human participants
 - use of human stem cells, human embryos, or their derivations
- APLAC (Administrative Panel on Lab Animal Care)
 - research & teaching activities involving live or dead vertebrate animals
- Controlled Laser Authorization
 - Class 3b or 4 lasers and laser systems
- Additional authorizations, such as Export Control, Materials Transfer Agreements, Data Use Agreements, Import Permits, Controlled Substances and Precursors, Select Agent/Toxin

Stanford's Current Approach to Building Access: Trust And Verify

- **Trust** that
 - researchers with card key access will stay away from campus research spaces unless approved for on-campus research functions.
- **Verify** with
 - walk-throughs.
 - records of building access.
- **PIs and lab members must**
 - be prepared for tighter restrictions on building access if required for security or public health.
 - update Essential Research SmartSheets if they wish to change their research activities.

Additional Considerations

- Researchers conducting on-campus research at this time must agree to follow:
 - [Guidance on Cleaning Laboratory Spaces and Adjoining Offices](#).
 - COVID-19 [Reporting and Tracking Guidelines](#), including the requirement to report COVID-19 tests and flu-like symptoms.
- When PIs update Essential Research SmartSheets, EH&S notifies the Department or Institute to prompt validation of the new functions.