

### Task Force Deliberations

A task force prepared guidance for clinical researchers at Rush because of the impending COVID-19 surge. As the number of cases in IL and at Rush have increased, the task force reconvened to plan for contingencies as we move into the period following this report.

The task force realizes that a “modified normalcy” that does not result in the full definition of Essential Research could be implemented if the anticipated surge results in the City/State moving to more tightened levels. Research operations may continue while precautions should be closely followed. Individual departments may move to a state of Essential Research rather than maintain modified normalcy if a team member tests positive and/or develops COVID-19 symptoms and has contacted others in the research space at Rush. It remains vital that leadership require vigilant adherence to precautions by all team members to ensure that research studies can continue at Rush.

We recognize that surrounding states will have different and varying guidelines for travel outside the state. Under the modified normalcy conditions, subjects newly identified for participation in a study who live in a state that is on a travel restriction list will still be able to travel to Rush to be screened, consented, and enrolled. If circumstances dictate the suspension of modified normalcy conditions at Rush, Essential Research may still follow this policy. Again, it is critical that all safety procedures are strictly followed.

We have revised the Essential Research criteria to now include research that benefits people with significant chronic conditions.

### Task Force Members

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The current [CDPH guidelines](#) include a revised Emergency Travel Order that reflects the changing nature of the pandemic and provides more specific guidance to travelers entering or returning to Chicago amid a surge in COVID-19 cases locally and nationally. Under the new system, states are placed in three categories – red, orange and yellow – based on the status of

the outbreak in the states and how the data compares to the situation in Chicago. The revised guidance is:

- **Yellow:** States with a rolling 7-day average less than 15 cases/day/100k residents.
  - No quarantine or pre-arrival test required. Maintain strict masking, social distancing and avoidance of in-person gatherings
- **Orange:** States have a rolling 7-day average **between** 15 cases/day/100k residents and the Chicago rolling 7-day average (currently 60)
  - 14-day quarantine OR **pre-arrival negative test** no more than 72 hours before arrival in Chicago with strict masking, social distancing and avoidance of in-person gatherings
- **Red:** States have a higher 7-day rolling average of positive cases/day/100k Chicago residents.
  - 14-day quarantine

Based on data available on November 10, 2020:

- 6 yellow states (no requirements): New York, California, New Hampshire, Maine, Hawaii, Vermont
- 31 orange states and Puerto Rico (must quarantine or receive a pre-arrival negative test result): see map below
- 12 red states (must quarantine): North Dakota, South Dakota, Iowa, Wisconsin, Nebraska, Wyoming, Montana, Minnesota, Utah, Idaho, Kansas, Indiana

Please check the [CDPH website](#) for the most recent guidance.

## **Essential Research**

### Criteria

1. Research that stands to benefit patients with acute or urgent conditions or **significant chronic conditions** requiring care, or
2. Research relevant to stemming or containing the COVID-19 pandemic, or
3. Research, which if paused or interrupted, poses a danger to participants from safety or intervention perspectives.

The task force recommended that any research which meets one of the three criteria above be classified as Essential Research.

An example of Essential Research would include a clinical treatment trial for patients with acute myocardial infarction or the majority of cancer research trials. In both of these domains, patients might benefit from participation in the trial and delay would reduce the likelihood of potential benefit.

An example of Research that is considered Non-Essential would be a study that seeks to diagnose children with neurodevelopmental disorders using a new assessment tool. Given that standard of care clinical assessment could diagnose a neurodevelopmental disorder, there is little immediate urgency to develop a new tool despite improvements in diagnostic accuracy that might be gained.

Decisions on what is considered essential research are made at the discretion of the study investigator at Rush. Any concerns regarding whether a study qualifies as essential research should be discussed with the department chair. If further discussion is needed in determining if a study qualifies as essential research, the Vice Provost for Research, Dr. Andrew Bean, may be contacted. Dr. Bean may request feedback from a committee of researchers available to address concerns regarding whether a study meets criteria of Essential Research.

Staff members with concerns about what is essential research (or essential visits in a research protocol) are encouraged to have open discussion with their study PI. If concerns continue to exist, they should be raised in an open and safe manner with the Department Chair and then with the Vice Provost for Research.

#### Guidance on Clinical Research as COVID-19 cases continue to increase

1. Any research that does not require in-person visits, and can be done remotely, should continue without restriction.
2. If there is a Stay-At-Home order issued either by the City of Chicago or the State of Illinois, Essential Research (as defined above) will be permitted to take place on RUSH campus. Participants who are already enrolled in studies who have routine clinical care on-campus can be seen per protocol.
3. Clinical research must adhere to the clinical protocols:
  - a. *Universal masks*
  - b. *Faceshield or goggles*
  - c. *Routine hand washing*
  - d. *Temperature & symptom screening for all participants*
4. When possible, clinical research activities should transition to virtual space and utilize video visits.
  - a. *PIs are directed to work with their sponsors or funding agencies to ascertain feasibility of this recommendation.*
  - b. *Documentation of these changes should be filed with the Rush IRB.*
  - c. *All research teams should prepare memos for their research files explaining the rationale for making or not making changes to the protocol in light of COVID-19.*
5. While these policies are implemented at the direction of the leadership, it is expected that Principal Investigators will have to make their own judgment as to where their research fits. It is advised that a committee be formed to review any deviations from these policies and recommend enforcement actions, if needed. Finally, this committee will serve as a resource should questions arise about the applicability of a particular study to the policies.

The default for site PIs is to not do research that does not meet the criteria for Essential Research if a City or State Stay-At-Home order is in place. Concerns regarding PIs not showing significant discretion in following the recommendations can be reported to the Office of Research Compliance (Stephanie Guzik) or the Institutional Review Board (John Cobb). Abuse of the discretionary authority granted to PIs may result in suspension of research activities if felt to be placing participants and staff at undue risk.

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levels. Research operations may continue while precautions should be closely followed. Individual departments may move to a state of Essential Research rather than maintain modified normalcy if a team member tests positive and/or develops COVID-19 symptoms and has contacted others in the research space at Rush. It remains vital that leadership require vigilant adherence to precautions by all team members to ensure that research studies can continue at Rush.

Under the modified normalcy conditions, subjects newly identified for participation in a study who live in a state that is on a travel restriction list will still be able to travel to Rush to be screened, consented and enrolled. If circumstances dictate the suspension of modified normalcy conditions at Rush, Essential Research may still follow this policy. Again, it is critical that all safety procedures must be strictly followed.

### Clinical Research After Stay-At-Home Orders End

1. After the end of Stay-At-Home orders, non-Essential Clinical Research can be resumed. All research staff must adhere to clinic protocols for management of participants – this will likely include symptom assessment, universal masking, and other precautions.
2. In the event that universal precautions or other current distancing protocols would impact research, the protocol should be reviewed by Infection Control, Occupational Health, and Research Compliance. *Recommendations from these groups should be forwarded to the Vice Provost for Research for final adjudication and decisions about if and how to proceed with the protocol.*
3. Research staff are directed to not participate in research activities involving participants if they exhibit any signs or symptoms of COVID-19 unless they are in a COVID-19 study.
4. In the event that a research staff member believes that they contracted COVID-19, and could have exposed participants to risk of infection (during a window or asymptomatic time period), this should be reported to the Rush IRB as an adverse event and appropriate documentation should be provided to explain the event and corrective actions.
5. Home visits / home & community-based research can be resumed with the caveat that attempts should be made to transition these research visits to video or telephone-based platforms.

### Student & Trainee Research

1. Any student or trainee clinical research that can be done remotely or via video/telephone-based visits can resume or continue.
2. Clinical trainees that are seeing patients in person may do limited studies at the discretion of their Chair or Section Chief who should assess the risk/benefit ratio for the particular project.
3. Patients in clinical research studies who are on campus for clinical care may also have clinical research visits with trainees at the discretion of the Chair or Section Chief.

4. All other student and trainee clinical research that involves human subjects will be suspended if conditions reach the criteria for Essential Research outlined above.
5. Finally, student or trainee research that meets the criteria for Essential Research can be considered for an exemption with approval from both the trainee's faculty supervisor and the Vice Provost for Research.

#### Criteria for faculty, staff, and trainee research

Clinical and laboratory research are cornerstones of Rush University's vital mission. The guidelines for the research environment during circumstances such as the COVID-19 pandemic are rooted in safety for the health and well-being of faculty, staff, trainees, and the public

Before faculty, staff, and trainees are approved to re-enter the clinical research or laboratory research environments, appropriate PPE must be available to all. To assure PPE is available, Department Chairs should communicate to their departments and/or Chris Kanakis regarding PPE needs so that appropriate orders can be placed in advance of personnel re-entry.

Faculty, staff, or trainees who have needs (health or otherwise) that would preclude them from participating in research at this time should seek accommodations according to the university guidelines for accommodations due to COVID-19 related issues. Personnel who have tested positive for COVID-19 should follow the Rush System for Health or University guidelines for personnel who test positive for COVID-19.

Personnel who test positive for COVID-19 or are having symptoms associated with COVID-19 infection must follow Rush's policy - <https://www.rushu.rush.edu/about/novel-coronavirus-covid-19-information/health>

#### Guidelines for faculty, staff, and trainees who have been infected with COVID-19

The following guidelines are in place to assure that faculty, staff, and trainees who perform research on campus, and who test positive for COVID-19, take the required precautions to assure they are taking care of themselves as well as protecting others around them. Faculty, staff, and trainees should adhere to the following guidelines if they have tested positive for COVID-19:

1. Faculty, staff, and trainees who test positive for COVID-19 must report this outcome to their supervisor and Rush Employee Corporate Health Services immediately.
2. Faculty, staff, and trainees who have tested positive for COVID-19 and/or in quarantine should comply with their treatment and inform their supervisor one day after they have been cleared to return to campus or research site. Faculty, staff, and trainees who are on campus should follow the guidelines for contact tracing according to Rush System for Health.
3. Faculty, staff, and trainees who intend to return to research environments on campus should provide Rush System's Return-To-Work form to Rush Employee Health.