

Recommendations from the Clinical Research Normalization Task Force

Submitted to Andrew Bean by Niranjan Karnik, on behalf of the Task Force, May 11, 2020, revised May 13, 2020 and May 17, 2020

Task Force Members

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Charge & Structure

On April 23, 2020 the task force received a charge to its chair, Niranjan Karnik, from Joshua Jacobs as follows: "To develop a plan for the normalization of clinical research throughout RUSH in the post-COVID pandemic time period."

The task force met on May 8, 2020 via a Zoom meeting to discuss recommendations.

Background

Since March 15, 2020, Rush University has been under the following policy in regards to clinical research: "In-person visits for clinical trials are only allowed if the visit is essential for the health and well-being of the participant. If such a visit is necessary, the visitor policy applies (no visitors will accompany the participant to the visit). If a scheduled visit is not essential for the participant's health or well-being, it must be conducted virtually or postponed."

Since this time exceptions have been made for Essential Research at the discretion of the President of the University.

Essential Research

The task force had a robust discussion about the definition of essential research and came up with the following outline:

1. Research that stands to benefit patients with acute or urgent 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 recommends 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 research essentialism criteria.

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.

Resumption of Clinical Research Under the Governor's Stay At Home Order

1. Any research that does not require in-person visits and can be done remotely can resume without restriction.
2. RUSH clinical operations are beginning to re-open on May 11th.
3. For the duration of the Governor's Stay At Home order, only 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.
4. Clinical research must adhere to the new clinical protocols:
 - a. *Universal masks*
 - b. *Routine hand washing*
 - c. *Temperature & symptom screening for all participants*
5. When possible, clinical research activities should be transitioned to the 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.*
6. 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 research essentialism criteria while the Governor's Stay At Home orders are 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.

Clinical Research After the Governor's Stay At Home Order Ends

1. After the end of the Stay At Home order, 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 clinical research performed by a student or trainee 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. All other trainee involvement in clinical research that involves human subjects is suspended until further notice.
4. 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 re-entry

Clinical and laboratory research are cornerstones of Rush University's vital mission. The guidelines for re-entry into 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 and medical center policies. 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.