Research FAQs

Human Subject Research

What is the procedure for pausing a study or certain elements of a study?
All changes to research protocol still need to be reviewed and approved by the IRB except for the incorporation of COVID-19 screening (https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html) as well as any measures needed to avoid an immediate apparent hazard to a patient/participant. The PI is responsible for making the assessment that there is a need for immediate action to protect the safety and well-being of the participant. If there is a need, the PI may make the change without first obtaining IRB approval. Note that this option is only available for changes that would impact participants already enrolled in the study; it is not appropriate to make such a change in order to enroll a new participant (for example exceptions to inclusion/exclusion criteria).

Follow the steps below if a change is made to prevent immediate hazard without IRB approval:
- Submit to the IRB within 5 working days of the change.
- The change and rationale for making it should be clearly documented in your research records (e.g. in a note to file).
- This change may apply to one subject or a group/all subjects in the research study.

These changes do NOT require prior IRB approval. But do require a submission to the IRB notifying the Committee of the change and rationale for the change.

Will the pause or change to the method of data collection be considered a protocol violation?
You should inform the study sponsor and/or the overall PI of the study of the modified procedures and what documentation requirements will need to be modified (e.g., changes to CRFs, video visits, etc.). Please submit those changes via amendment to the IRB for consideration.

The regulations allow implementation of a change to study procedures without prospective IRB approval when it is necessary to avoid imminent hazards to subjects. But IRB approval must be obtained as soon as it is feasible.

If I am pausing study procedures, do I need to notify the IRB of Record, for studies relying on an external IRB, in addition to responding to the questions from the Rush IRB?
Yes, as soon as feasible. The regulations allow implementation of a change to study procedures without prospective IRB approval when it is necessary to avoid imminent hazards to subjects. The IRB of Record will need to approve resumption of study procedures. Please call Crista
Brawley (312-942-7276) or email cristal_brawley@rush.edu for questions related to a specific study.

**May we continue to collect data and follow up with subjects by telephone when in-person data collection has been paused?**
Yes. Following up with subjects is encouraged to monitor for safety events during the pause. Rationale: There is no increased risk to subjects relating to COVID-19.

**I am a PI of an investigational drug/device trial. Do I need to pause my trial?**
This is at the discretion of the PI considering the risk/benefit ratio to the subjects and research support staff. It is assumed that such trials with investigational treatments, including drugs and devices, provide potential for benefit.

**I am conducting FDA-regulated research for which I am the sponsor of an IND or IDE. Do I need to notify the FDA if I pause my study?**
Yes. The FDA will need to be notified. Contact Crista Brawley (312-942-7276 or cristal_brawley@rush.edu) for specific guidance and information on the notification process.

**Should research participants come to Rush for scheduled follow-up visits?**
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 if possible. Exceptions include patients undergoing chemotherapy, transfusions or infusions; and patients who require help for safety purposes. If a scheduled visit is not essential for the participant’s health or well-being, it must be conducted virtually or postponed.

**May we allow sponsor monitors to audit their sponsored studies on site?**
RUMC is immediately suspending on-site access to any of RUMC’s facilities by research monitors until further notice. The Office of Research Affairs is evaluating the need and ability for remote access to facilitate continued monitoring using the electronic medical record.

**May we enroll new subjects on existing studies?**
This should be decided on a study-by-study basis and new enrollments may result in minor protocol deviations. Minor protocol deviations which do not have the potential to negatively impact participant safety or integrity of study data (ability to draw conclusions from the study data) or affect subject’s willingness to participate in the study. Minor protocol deviations could include conducting a study visit virtually (by remote means) or outside of window, omitting a specific research procedure or collecting questionnaire/assessment data over the phone instead of in-person. Minor protocol deviations are reported to the IRB at time of Continuing Review through submission of a Deviation Log. Rationale: The risk/benefit ratio for subjects may have changed from the time at which the protocol was reviewed and approved.

**Should we screen participants for symptoms of COVID-19 prior to a study visit?**
Yes, all participants should be screened by phone in advance of their visit. Screening questions:
1. In the last month, have you been in contact with someone who was confirmed or suspected of having Coronavirus/COVID-19? (Yes = positive screen, No, Unsure)
2. Do you have any of these symptoms currently: cough, shortness of breath, fever? Yes to any symptom = positive screen
3. Have you traveled internationally in the last month? Yes = positive screen
If a participant has a positive screen: We recommend the participant schedule a video visit with a provider to further evaluate their symptoms. The visit is free of charge, and they can schedule the visit via MyChart or MyRushMobile app. If they do not have access, call Infection Control at 312-942-3060 or page 7424 for specific directions for that participant.

**Should the 3 pre-visit screening questions be included as supporting documentation in the subject's study binder?**

Only if you choose to do so. This is not considered human subjects research or part of the study. You do not need IRB Approval to screen the participants in this manner. This is an institutional policy being implemented for all patients regardless of whether they are research subjects or not.

**What do I do if a patient/participant shows signs of being ill (clinical screen, fever, cough, etc.) when coming in for a research visit?**

Please have the patient/participant wear a mask, sequester the patient/participant in a private room/area, and page Infection Control at 7424 or call Infection Control at 312-942-3060 for further instructions.

**I am a PI of an investigator-initiated protocol that is multicenter. Should my site suspend their study-related activities?**

Participating sites of multicenter IITs should adhere to their individual site directives. RUMC staff that oversee the conduct of those sites participating in research related activities should be in contact with the participating site to understand the site’s plan. Protocol adherence and disruption to enrollment during this time should be discussed per protocol per site. Investigators should decide on a case-by-case basis how to handle the protocol disruption and communicate effectively to regulatory agencies as described above. Contact information for participating sites should be provided by the lead investigative team.

**May we enroll new subjects while the IRB is making the determination whether to keep enrollment open?**

Yes.

Rationale: The presumption is that most PI analyses of risks and benefits will be accepted by the IRB. The IRB will review these case-by-case situations very rapidly.

**May I initiate a new trial that involves a drug or device?**

Routine IRB meetings are occurring as scheduled (every Monday and Wednesday), just in a virtual manner. If you have a new study to submit, please do so via the Rush Research Portal. Of note, COVID-19 specific studies will be given priority.

If your study is specific to the COVID-19 pandemic, please contact Crista Brawly (crista_brawley@rush.edu) immediately for direction. Studies of this nature will be decided by the IRB on a trial-by-trial basis. The PI should provide a revised risk-benefit statement that explicitly takes the COVID-19 risks into account.

**If my study is being conducted off-site, may it continue?**

Regardless of location, if a scheduled visit is not essential for the participant’s health or well-being, it must be conducted virtually or postponed.

**If my study is being conducted entirely during an inpatient admission, may it continue?**

Yes, it may.
For study patients with dementia coming in for essential research visits, will the visitor policy be waived so their caregiver can assist the patient and provide information to the physician? In this case, yes. If the patient cannot travel alone or is disabled, please use your best judgement.

For industry drug trials, it is important that the subject remain on investigational product (and have adequate supply) and that their labs are monitored. Does this constitute being best for the health and well-being of the patient? Yes, this would qualify as essential to continue.

Are IRB committees meeting on regular schedules during this disruption? Yes, we are meeting as scheduled on Mondays and Wednesdays (virtually), and as needed to handle the volume of requests.

Should we document in the subject’s binder that the study visit is necessary or not? Yes. Documentation during this time will be critical to the future. Please document all decisions made and processes followed.

I presume virtual research visits will require consultation and approval from the sponsor? If approved, are we required to submit an amendment to the IRB? Yes, an amendment is required for the study in general, but not for each patient.

Can we consent new patients virtually for non-treatment studies? Please submit an IRB Amendment to the IRB for approval to proceed with the research in that direction. The IRB will make the decision based on each individual study.

Will the collection and processing of study labs be centralized? No, not at this time. Please work with your routine clinic to determine the process for study lab collection.

The FAQs say we should stop in person visits, and we need to submit an IRB amendment for such stopped visit. Is this correct? Yes.

Are you recommending that new enrollments should be suspended? Please use your best judgement regarding the type of study, feasibility of enrolling new subjects, and the study staff required to enroll when making the decision to enroll new subjects or not.

Will an updated letter be sent out for us to send to sponsors stating that we cannot have monitors on site? The letter is available on the Rush Research Portal for your use.

If we submit a generic letter from a sponsor stating that virtual visits are allowed, do we need to follow up with the IRB when virtual visits actually occur? No. If you obtain IRB approval to perform virtual visits, then the study is approved.

In cases of non-pharmacologic trials in which visits are being postponed, what date should we target to reschedule visits? It is unknown at this time.
If most of our study visits are normally in-person, but we have always had the option for telephone visits which are used periodically, do we need an IRB amendment? Or are we fine since our study is already set up to handle phone visits?
You may perform telephone visits as per the protocol and IRB approval.

Are there recommended platforms for virtual safety check-ins or online platforms to contact research participants? Should we be using our personal cell phones?
MyChart is required for video visits on the clinical side. Contact Information Services by emailing 3CLAS@rush.edu to assist with online platforms and set-up if needed (WebEx and Zoom).

Research Pharmacy
I do not see any FAQs related to IP/Study drugs and the research pharmacy.
This is being determined on a study-by-study basis since not all studies funnel through the same pharmacy.

What access do staff have to the research pharmacy?
Research pharmacists and pharmacy personnel have full access. No other Rush personnel or any others will have access at this time.

Are there any restrictions related to research pharmacy workflows? Hours of operation? IP order submissions and dispensing guidelines?
Every study team should discuss the concerns with the appropriate pharmacy and pharmacy personnel involved to address issues.

If IP is dispensed from the research pharmacy who will manage the shipment of IP (if applicable) by courier to subjects? The research pharmacy or the study staff? What documentation, if any is needed? What about temp control of the IP?
A plan should be made with the appropriate pharmacy and pharmacy personnel to determine the answers to these questions on a study-by-study basis. Of note, for several drug studies the sponsor is arranging for study drug shipment directly to participants’ homes. Please be in touch with your sponsors, and submit any IRB amendments with communication/process changes as necessary.

Grants
I'm experiencing delayed subject recruitment and/or cancellations of scheduled follow-up visits with my study participants and it is negatively affecting the progress of my grant. What should I do?
For programmatic issues affecting your study, we strongly recommend you speak with Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) in ORA: Sponsored Programs Administration Office first, and she may recommend that you speak with your agency Program Official or other sponsor contact. If any issues should persist, they may need to be reported in future progress reports. Please coordinate any such actions with Jennifer Garcia directly.

What if I am home sick and can't work on my project? Can my salary still be charged to the grant?
Yes. Pursuant to Rush’s indirect cost rate agreement with the federal government, sick leave and other paid absences that are permitted under Rush University Medical Center policy may be charged to the grant. Please note, Federal agencies require notification if the PI or Key
Personnel named in the award will be absent of the project for greater than 90 days. While this is not expected, be mindful of this prior approval requirement and notify Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) for guidance.

My study may be impacted by the pause, which could lead to delays in completing my study by the end of the project period. What should I do?
Most federal sponsors, including NIH, allow for a one-time no cost extension for 12 months at the end of the project. Please discuss your specific project with your grants specialist in the ORA: Sponsored Programs Administration Office or Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) directly, who will provide guidance on the options available to you.

As noted above: Industry sponsors & other institutions with which Rush is contracting, would need to be notified regarding any interruption in study activities. The Office of Legal Affairs: Research Agreements, under Heather Kartsounes (Heather_A_Kartsounes@rush.edu) and Erin Blackmon (Erin_Blackmon@rush.edu), can initiate this correspondence and need to be notified of any such communication.

Should NIH or other sponsors (government, industry, or non-profit) be notified that select protocol activities or in-person visits of a funded research study will be paused?
When a Federal or Foundation study has been identified, please contact the ORA: Sponsored Programs Administration Office or Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) directly. SPA will coordinate and communicate an official response/update to the Sponsor. For your industry-sponsored studies, please contact The Office of Legal Affairs: Research Agreements, under Heather Kartsounes (Heather_A_Kartsounes@rush.edu) and Erin Blackmon (Erin_Blackmon@rush.edu).

I am self-isolated, quarantined, and/or at home caring for a sick family member and am unable to submit my grant by the stated deadline. May I request an extension?
Most federal agencies, including NIH and NSF, do not grant prior approval for late submissions; however, there are existing policies that address extenuating circumstances. Current NIH guidance can be located at NOT-OD-15-039 and Special Exceptions to NSF’s Deadline Date Policy (PAPPG 19-1). We strongly encourage you to discuss your specific situation with ORA: Sponsored Programs Administration Office or Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) directly.

Also, see the Guide Notices below for more information:
- NIH Late Application Policy Due to Public Health Emergency for COVID-19
- Flexibilities Available to Applicants and Recipients Affected by COVID-19
- General Frequently Asked Questions – Proposal Submission and Award Management Related to COVID-19
- NSF FAQs #16 and #17

What should I do if I have an upcoming Progress Report due, but I will be unable to submit it on time due to COVID-19?
If you are unable to complete and submit the Research Progress Performance Reports (RPPR) by the scheduled due date, due to COVID-19, please be sure to contact a member of the SPA team or Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) directly so the assigned grants management and/or program official can be notified to let them know the reports will be late. NIH will accept these late reports but will delay issuing grant awards until the reports are received and accepted by the appropriate Institute or Center (IC).
Where can I get more information on sponsor-specific policies concerning disasters and emergencies?
See NIH Extramural Response to Natural Disasters and Other Emergencies: https://grants.nih.gov/grants/natural_disasters.htm
See NSF Responses to Natural Disasters: https://www.nsf.gov/naturaldisasters/

Will I be able to submit for grants or will my sponsored projects submissions be processed during this time?
Yes. Please continue to work with the ORA: Sponsored Programs Administration Office or Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) directly for all submissions.

If we need a computer to work from home, can we buy one online independently (not through IS) to be delivered to our homes and then be reimbursed later from a grant for that purchase?
Contact Information Services by emailing 3CLAS@rush.edu to assist with loaning out a laptop. Please continue to work with the ORA: Sponsored Programs Administration Office or Jennifer Garcia (312-942-3554 or Jennifer_Garcia@rush.edu) directly for allowable expenses on grants.

Are there any NIH funding delays that you are aware of?
Not that we are aware of at this time, but it is a fluid situation.

Basic/Translational Laboratory Research
All faculty and lab directors should develop a research continuity plan. Consider how the work of your groups can be slowed for the coming weeks and what steps would be required if the work was placed completely on hold with short notice. Non-essential staff, students and postdocs in your groups must work from home. Provide work that can be achieved at home. Require that if anyone in the group is sick that they do not come to work. Establish a system by which you, and members of the lab, can check the status of each other. Make sure everyone has the necessary contact information.

May I require employees in my group or lab to work on-site?
Please limit the number of individuals on campus in research laboratories to “essential” personnel only, as defined by the department chair in collaboration with the principal investigator. Essential personnel may include workers taking care of mice, cell lines, and checking on essential lab functions including refrigerators, freezers, and other responsibilities. All other lab personnel must work remotely until further notice.

Creating Contingency Plans for Labs:
Consider how the work of your groups can be slowed for the coming weeks.

1. **What assumptions should I make and what timeframe should I plan for?**
   - Assumptions that you can use for planning, based on a worst-case scenario with widespread COVID-19 communal transmission:
     - A significant percentage of your laboratory workforce will be out sick or unable to come to work.
     - Essential research infrastructure, such as power and telecommunications, will be maintained.
The Animal Center will maintain critical functions. Orders for critical supplies may be significantly delayed. Processing of visas by the federal government will be delayed, resulting in delayed appointments. International, and perhaps domestic, travel will be restricted. Core facilities and other fee-for-service resources may have limited, delayed or no access. Repairs performed by Facilities and other service providers may be delayed. Decontamination of your workspace may be necessary in the event of a local illness. The university will communicate any disruptions to laboratory access. These disruptions may persist for weeks or months.

2. What steps should PIs and research managers take to create a plan for research continuity?
   - Immediately update your laboratory member contact lists with current emails and phone numbers. Share them electronically and in paper form with each laboratory member.
   - Update your contact list of important non-laboratory support staff, vendors, and suppliers. Circulate this list electronically and in paper form with each laboratory member and with your lead administrator.
   - Assess and prioritize critical laboratory activities.
   - Ensure staff have the necessary and appropriate training to perform critical laboratory functions. Cross-train research staff to fill in for others who may be out sick or unable to come to work.
     - Consider documenting critical functions with step-by-step instructions.
   - Identify in advance any research experiments that can be ramped down, curtailed, or delayed.
   - Identify procedures and processes that require regular personnel attention (e.g., cell culture maintenance, animal studies).
     - If your laboratory has essential functions that must be continued under any circumstances, please immediately identify the key laboratory members, PPE, and equipment needed to perform these functions. Provide this information to your lead administrator.
   - Identify personnel able to safely perform essential activities.
   - Coordinate with colleagues who have similar research activities to develop redundancies and ensure coverage of critical activities.
   - Review contingency plans and emergency procedures with researchers and staff.
   - Maintain a sufficient inventory of critical supplies that may be impacted by global shipping delays.
   - Consider installing remote control monitoring devices for critical equipment (e.g., -80C freezers, liquid nitrogen storage dewars, incubators).
   - Communicate significant planned absences and/or laboratory closures to your Safety Advisors, business offices, and other key administrative units.

3. What steps can I take now to mitigate or prepare for supply shortages or disruptions in vendor services?
   - Identify your critical supplies.
     - If possible, order a two-month supply of your critical supplies. Have a system to reorder critical supplies when your inventory gets low.
Identify secondary sources of your critical supplies in case there is a disruption of your usual supply chain.

- Train multiple laboratory members to order supplies.
- Ask other laboratories if you can share or borrow supplies for your critical experiments.

What plans should I make for long term experiments, such as experiments that start and stop over a period of weeks, months or years?
No plans should be made at this time to start new long-term experiments.

What can I take out of my laboratory?
All materials in the laboratory are considered the property of RUMC. Chain of custody must be properly documented and is required prior to transfer. PIs are responsible for the care and use of research data at all times.

- You should arrange with, and receive approval from, your PI or laboratory manager to take copies of laboratory notebooks, data storage devices, software dongle keys, or laptops that help you work remotely.
- Under no circumstances should researchers take materials other than laptops, data storage devices, or notebooks offsite (e.g., to their homes). All essential research activity must continue within the confines of an appropriate laboratory space to ensure research continuity and the safety of laboratory staff.
- Under no circumstances is it appropriate to remove animals from IACUC approved housing or research spaces. You should contact Animal Research Facility with any questions or concerns.
- Under no circumstances is it appropriate to remove chemicals or reagents from the laboratories.

What do I do if I have animals in the Comparative Research Facility (CRC): Animal Facility?
The Animal Research Facility will maintain all animals throughout this time. Please send all questions directly to Jeff Oswald (Jeffrey_P_Oswald@rush.edu) and Anthony Davis (Anthony_D_Davis@rush.edu).

I am supposed to travel to a field site for research purposes soon. Do I need to cancel the trip?
Yes. As of March 5, 2020, Rush officially suspended all international and domestic business travel, including attendance at any local professional conferences.

I planned to host a visiting scholar this spring/summer. Should I cancel these plans?
As of March 5, 2020, Rush officially suspended all international and domestic business travel. This recommendation is ongoing until we lift the suspension.

What expectations are there for monitoring lab freezer temperatures that contain research samples only (e.g., not samples used for clinical/diagnostic purposes). Should we have staff members monitor those freezers that are not being remotely monitored?
Now is the time for collaboration with staff in surrounding labs on your floor. Please look out for your neighbors and take care of each other’s equipment. Have your essential personnel walk the floor during the time that they are on campus to listen for alarms and look for water on the floor. Please ensure that labs know how to contact each other in case of emergencies.
How can hourly research staff instructed to stay home receive a full paycheck if their work can't be done remotely?
Please contact your manager or HR for questions about hourly staff.

Do I need to be specified as "essential" in order to enter Rush?
Yes.

Will liquid nitrogen be delivered as usual?
At this time, we do not have any new information on supply chain deliveries.

Can you clarify whether students are supposed to come to the laboratory?
Students should not come to the laboratory, unless they are deemed essential by their PI. Essential students may be MS or PhD students in the IBS Program. Since this is close to the end of the term, alternative assignments should be given to students if possible. Examples of these activities include: data analysis, reading papers, or writing manuscripts.

Until when are the research labs expected to have only essential lab personnel visit the lab to maintain cell culture, etc.?
We do not know at this time. This is fluid situation.

What about experiments that must be done because they require animals (mice) that are aged and the animals are soon to reach that window of age?
Experiments that require significant laboratory time (e.g. behavioral, physiological, biochemical) should be paused at this time. The risk to laboratory staff should be weighed against the ability to delay these experiments for weeks. The health of your staff is paramount.

What about maintenance of cell lines and mouse strains?
Identify whether your laboratory has critical cell lines or strains that would result in considerable delays to your research productivity if they were frozen. If possible, minimize them by combining them or ramping down lower-priority activities. Cross train members of the laboratory to perform maintenance activities. Draft detailed maintenance procedures, so that an inexperienced (but qualified) person can perform maintenance activities. Ask a researcher in another laboratory to act as a backup for these activities.

We have human tissue, coming from abroad every week. These are unique samples from unique patients. They require our work when they arrive. The specialized people that do this work, can they be considered "essential"?
Yes.

When would we be redeployed to help with COVID-19? How would we be contacted?
RUMC will contact you if you are needed for redeployment. These decisions are still fluid and changing.