

Process for Preparing Plans for Johns Hopkins University School of Medicine Principal Investigators who Supervise Staff involved in Human Participant Research

This document describes the process for completing the form for workspace for clinical research staff.

The form will be completed online.
A copy of the form is available at the end of this document.

Guiding Principles consistent with JHU guidelines:

- Research activities that can be accomplished appropriately at home via telework should be continued at home.
- Maintain low density in work spaces to minimize risk to staff while allowing human subjects research to restart per the phased plan.
- Provide a safe environment for research staff to work including access to personal protective equipment, social distancing per guidelines and appropriate training.
- Assure work environments meet regular cleaning standards and have plans for appropriate cleaning should a staff or participant be identified as COVID+.
- Every individual returning to work on-site must conduct personal safety practices of daily reporting of symptoms, universal face coverings, social distancing, and hand washing.
- Research staff in clinical settings will follow up-to-date guidance for working in those settings.
- Research staff working in office and other environments must maintain social distancing practices of being 6 feet apart and masking unless working alone in private offices with closed doors.

Key points for the form / FAQ:

- *How does this form relate to reopening my individual study protocols?*
 - This form is separate from the processes to submit human participant protocols for review for reopening. The documents are covering different aspects of human participant research.
- *What type of space is this form asking about?*
 - The form focuses on “non-clinical” space for staff/trainees meaning space which is not formally managed clinical space. We are defining clinical space as space under the supervision of health system clinical operations in terms of patient safety, equipment and cleaning.

- *Who is covered under this form?*
 - For space, principal investigators will report on staff and trainees where non-clinical space is their assigned primary work space.
 - Staff who were already designated essential research personnel during COVID should still be listed. They can continue their current work before these space plans are approved.
 - Staff working exclusively on COVID studies should also be listed. They can continue their current work before these space plans are approved.
 - Principal investigators will also report names of clinical research staff who work only in formally managed clinical space so that we may build a database of all clinical research staff in the SOM. However, we are not evaluating space plans for those staff.
- *What does the term assigned workspaces mean?*
 - Assigned workspace is where people sit, like in an office or a carrel.
- *What about rooms where study participants are seen?*
 - This form primarily asks for information for staff. The Human Subjects Research Protocol Restart Committee that reviews protocols will explicitly review the research participant experience and availability of resources to support the research. However, if staff have their primary workspace in a room where participants will be seen, please include this space on the form.

- *I share my staff with other principal investigators. Who fills out the form?*
 - For PIs who share or pool staff, the PI who has the primary responsibility for the oversight of the research staff person should submit the plan.
 - The PI completing the form will list the other PIs the form covers.

- *May I have my research manager or administrator fill out this form?*
 - The PI fills out the form, as there are checkboxes the PI needs to answer with regard to staff safety in the work place.

- *What distancing requirements are there for workspaces? Are they the same for as for lab research?*
 - We are focusing on having members of research teams be at least six feet apart from one another in all directions.

- *I already submitted my plans with the laboratory plan submission process. What should I do?*
 - If your staff were already included on approved lab plans then you don't need to repeat the space assessment for clinical research, however please submit the form with clinical research staff names only so that we can build a database of those staff.
 - If not all staff were included please submit space plans for those clinical research staff who were not included in the lab plans.

- *Are clinical research staff being linked to the lab's Density app?*
 - No.

- *Where do I obtain PPE?*
 - Your department will have some PPE and additional PPE can be purchased for your research team.

- *Can I save this form and finish it later? What if I have to edit after I upload it?*
 - Yes, you can save the form and continue it later. (Save by pressing next and return to the survey in the same browser and device in which you started the survey.)
 - You may resubmit the form as a new version and provide an explanation to describe the changes made since the previous submission.

- *Who do I ask if I have questions about this form?*
 - For technical questions please contact Mia Terkowitz, mterkow1@jhmi.edu.
 - For questions about your research space or the review process please contact your Departmental Restart Committee representative or Gail Daumit gdaumit@jhmi.edu

- *What do I need to know to make filling out the form most efficient?*

Before filling out the form these would be helpful:

1. Decide which PI will fill out the form if there are shared research staff. If reporting for other PIs, the reporting PI will need to list the JHEDs of the other PIs.
2. Collect JHEDs for research staff and trainees who have assigned workspaces.
3. Floor plans of your space will be helpful for you to review as you fill out the form. Floor plans are only required to be uploaded if you are requesting an exception to the 6 feet social distancing requirement.
4. Consider which are the “non-clinical” (see above) workspaces for your team. We are considering work spaces to be areas of floors, suites, etc.
5. For each workspace, you will be asked the number of private offices, shared offices and open shared work areas. You will need to consider where desks and carrels are in shared spaces and how far apart they are from each other. For shared offices and shared open areas you will be asked to estimate the square feet.

Survey Form
Plans for Johns Hopkins University School of Medicine Principal Investigators
who Supervise Staff involved in Human Participant Research

The university is adopting a phased plan for re-opening human participant research in line with its overall plan for re-opening. Individual research protocols will be reviewed for re-opening by committees at each school. This form is targeting the plans for providing a safe work space for clinical research staff. This space plan only covers the space which is not formally managed clinical space, or “non-clinical space”. We are defining clinical space as space under the supervision of health system clinical operations in terms of patient safety, equipment and cleaning.

When completing this form, principal investigators should consider all research staff who report to them as well as trainees where “non-clinical” space is their primary workspace. Principal investigators should report on all staff including those already designated as essential personnel and those working exclusively on COVID studies.

Please note, this form additionally asks for names of clinical research staff who work only in formally managed clinical space so that we may build a database of all clinical research staff in the SOM. However, we are not evaluating space plans for those staff.

Guiding Principles Consistent with JHU Guidelines:

- Research activities that can be accomplished appropriately at home via telework should be continued at home.
- Maintain low density in work spaces to minimize risk to staff while allowing human subjects research to restart per the phased plan.
- Provide a safe environment for research staff to work including access to personal protective equipment, social distancing per guidelines and appropriate training.
- Assure work environments meet regular cleaning standards and have plans for appropriate cleaning should a staff or participant be identified as COVID+.
- Every individual returning to work on-site must conduct personal safety practices of daily reporting of symptoms, universal face coverings, social distancing, and hand washing.
- Research staff in clinical settings will follow up-to-date guidance for working in those settings.
- Research staff working in office and other environments must maintain social distancing practices of being 6 feet apart and masking unless working alone in private offices with closed doors.

Process

1. Principal investigators complete this form online.
2. When completed, the form will be transmitted to principal investigator’s department.
3. Departmental Research Restart Committees will review the submissions with input as needed from the School of Medicine.
4. After review the Principal investigator will receive an email confirming the plan has approval.

Additional Information about This Form

- This form is separate from the processes to submit your human participant protocols for review for reopening. The documents are covering different aspects of human participant research.

- This form primarily asks for information on staff. The Human Subjects Research Protocol Restart Committee that reviews protocols will explicitly review the research participant experience and availability of clinical resources to support the research.
- For PIs who share or pool staff, the PI who has the primary responsibility for the oversight of the research staff should submit the plan.
- After review and any needed modifications, the Principal Investigator will receive an email confirming the plan has approval.
- If you have questions about this survey, please contact your Departmental Research Restart Review Committee or Gail Daumit, gdaumit@jhmi.edu. For technical questions about the survey, please contact Mia Terkowitz, mterkow1@jhmi.edu.

If you are not able to complete this form in one sitting, you may return to it later by pressing "next" to save your responses and re-opening the form in the same device and browser in which you started the form. If you are submitting a new version of the form, you will be asked to complete the entire form and to specify a version number.

1. Department (select)

2. Principal Investigator (PI): *First and Last Name*

3. JHED ID of PI: _____

4. Email of PI: *Outcome of plan review will be sent to this email.*

Please specify whether this is the first time you are completing this form. If not, select "no" and provide a version number for the current form.

- Yes
- No (please specify a version number for the current form) _____

[If no:] Why are you submitting a new version of the form (describe changes): [Text Box]

5. If you share research staff and trainees with other PIs and are reporting for those PIs, please list the names and JHED IDs of the **PIs** below: [Table]

Non-Clinical Workspaces

6a. Names [First Last] and JHED IDs of all research team members (staff and trainees) who have assigned work space in non-clinical space [Table]

Thank you for reporting on who in your research team is in non-clinical space. Before you will describe your non-clinical workspaces, please list any clinical research staff you supervise who are only based in clinically managed space. Write the name and JHED ID of each clinical research staff member in the space below (e.g., Joanna Smith, Jsmith1; Anna Smith, ASmith12). [Text Box]

Which types of staff did you report on in the above questions? If you only reported on clinical research staff based in clinically managed space, you will be directed to the end of the survey.

- Research team members (staff and trainees) who have assigned work space in non-clinical space
 - Clinical research staff you supervise who are only based in clinically managed space
 - All of the above
-

Description of Non-clinical workspaces

The next section will ask you to describe your workspace(s) that are not overseen by the clinical operations group. For investigators with more than one workspace, we will ask you to report on each of your workspaces separately. Providing information on at least one work space is required.

7. Please specify the number of workspaces in numeric form below. (e.g., If a study team has offices in three separate buildings or floors, you should indicate that you have three workspaces regardless of the number of offices within each workspace). You will be asked to fill out Section 2 once for each workspace.

Section II. Non-clinical Workspaces Description The following set of questions will be repeated for each workspace:

1. Location

Building Name or address _____

Suite/Room Number and/or Floor _____

2. Does this workspace include any of the following? Check ALL that apply and specify the number of spaces within this workspace that fit this description.

Private office(s) with door (please indicate how many)

Office shared with another person(s) (This could also include ante-rooms where a person's office is a walk through to another office) (please indicate how many)

Open shared work areas (e.g., area with cubicles) (please indicate the number of areas)

2a. For each office shared with another person(s) within this workspace, please fill in the information below. [Up to 15 offices may be listed.]

	Office #	# of desks/carrels	# of people on-site in this space pre-COVID	# of people planned to sit in the space at one time during this phase (maintaining a minimum of 6 ft. physical distancing)	Approximate size of space in sq. feet.
1.					
2.					

2b. For each open shared work areas within this workspace, please fill in the information below.
 [Up to 15 open shared work areas may be listed.]

	Name of Space (e.g., floor number)	# of desks/carrels	# of people on-site in this space pre-COVID	# of people planned to sit in the space at one time during this phase (maintaining a minimum of 6 ft. physical distancing)	Approximate size of space in sq. feet.
1.					
2.					

3. Please describe any other considerations or relevant details about this workspace. (e.g., You can easily separate carrels to 6 feet or more because carrels are not connected, carrels are high and not low, shields will be added, will remove carrels from near entrance so less there will be more space for people walking by etc.)

Thank you for filling out Section 2 of this form for this workspace. If you indicated that you have an additional workspace, you will be directed to fill out this section for the next workspace.

Section III. The following questions apply to all of your non-clinical workspaces:

1. Check all the steps you will utilize to ensure that there will be at least 6 feet between staff:

- Desks/carrels will be moved/reconfigured
- Empty desks/carrels will be blocked off to ensure proper distancing between staff members
- Study team members will not work in the space at the same time (e.g., shifts, mostly working at home) to ensure social distancing
- Other (specify below) _____
- Not Applicable (Private workspaces or rooms currently have 6 feet of space between desks on all sides.)

2. Are you requesting an exception to the 6 feet distancing approach for any of your workspace(s)?

- Yes
- No

2a. If yes, please explain why an exception is needed and for which space(s). (The next question will ask you to upload a floor plan or diagram of the space.)

3. If an exception is requested you must upload a floor plan. Otherwise, floorplans are not required but may be uploaded if you think it may be helpful to explain your responses.

If you are requesting an exception and uploading a floor plan, clearly label seating arrangements in the floor plan. Please include the PI's name, the date, and FP for "floor plan" in the name of the attachment (e.g., FP_PI_061020).

4. By checking the following boxes, I certify that before any staff enter their work space:

	I certify that this is true.
I have discussed the reopening plan with all members of the research team.	<input type="checkbox"/>
I have communicated with all research team members that they can speak with me or another departmental representative about any concerns related to their work space.	<input type="checkbox"/>
I understand that this reopening plan will be reviewed by my Department's Research Restart Committee and may need to be modified before approval.	<input type="checkbox"/>
Research team members will wear face coverings at all times while on-site except in private office with closed door or while eating.	<input type="checkbox"/>
I am providing appropriate personal protective equipment for research team members and ensuring appropriate training per guidelines including for any participant interaction that will occur.	<input type="checkbox"/>
I have discussed with my research team the importance of personal safety practices of daily symptom reporting, universal face coverings, social distancing, and handwashing and ensured training in these areas.	<input type="checkbox"/>
I will have the research team minimize time needed on-site and continue to have research activities performed appropriately through telework when possible.	<input type="checkbox"/>
I have developed a plan and work schedule based on size and layout of space for physical distancing to keep a 6-foot distance between research members during normal work interactions.	<input type="checkbox"/>
If applicable, I have discussed space arrangements with my faculty colleagues with whom I share research space to minimize the research team members' risk and ensure appropriate social distancing.	<input type="checkbox"/>
The research space has protocols for use and cleaning of all shared equipment and surfaces. The research space has regular cleaning practices in place.	<input type="checkbox"/>
The research program will follow all departmental and institutional regulations for use of shared rooms and other on-campus activities.	<input type="checkbox"/>
My research team members will follow prevailing guidelines regarding infection control, including not having personnel come to work who have any symptoms of illness, and following current JHU guidelines if research group members test positive for COVID-19.	<input type="checkbox"/>

Please review your responses before clicking next to submit.