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| **Section A: General Information** |

1. Department/Center: DEPARTMENT
2. Division: DIVISION
3. Research Group/PI Name: PI NAME or GROUP NAME

*“Research Group/PI Name” represents the PI or research group submitting this Portfolio Plan for consideration*

1. Research Group Contact Name *(if applicable)*: same
2. PI / Research Group Contact Email: principalinvestigator@umn.edu

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| **Section B: Mitigation of Risk (Employee-Focused)** |
| 1. Please complete the “Personnel Details” tab on the Data Form for compliance with the Request for Return to On-Site Work Authorization under the [University’s Sunrise Plan](https://safe-campus.umn.edu/sunrise-plan).

If you have already submitted a Sunrise Plan under the [Medical School/OACA Sunrise Implementation Process](https://clinicalaffairs.umn.edu/resources/med-school-oaca-sunrise-plan) and received approval for your dry or wet lab space that you use for your clinical research, you do not need to complete questions 7-10. Please attach the approved sunrise plan and submit the information requested in the “Personnel Details” tab for the Clinical Research Sunrise Implementation process. 1. Before coming to work, every employee must attest they have no symptoms of COVID-19, have taken their temperature and it is <100.4˚F. Please describe the process for meeting this requirement. It is important to note, employee temperature readings cannot be recorded or documented.
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| Employees will be asked to attest from home that they have no symptoms of covid-19, have taken their temperature, and that it is < 100.4 F on a google doc ([COVID-19 Attestation](https://docs.google.com/forms/d/e/1FAIpQLScAzbzRK0DDXraXsbUBo7I0dDshujlqcI5ZGYdd42zoSLnecQ/viewform?usp=sf_link)). We will provide a simple check off link that will allow time stamping. We will not ask that the temperature be recorded or documented.The 3 points below will be reported to, discussed with, and supervised by the PI on a case by case basis.1) Return to work is voluntary.  Employees who are uncomfortable returning to work, for medical or other reasons, will not be required to do so.  2) Individuals with a known exposure (household or work contact) will not be allowed to return to work until 2 weeks has passed, and they have negative PCR test (if testing is available to them).  3) Any employee who is symptomatic should remain home in quarantine until they can safely return to work.Taken together, **we will follow the** [**Overview of the actions all on-campus employees must take**](https://clinicalaffairs.umn.edu/resources/guidance-essential-and-returning-employees)provided by the University’s Office of Academic Clinical Affairs, as well as [**President Gabel’s Sunrise Plan**](https://safe-campus.umn.edu/sunrise-plan)**.** If an employee becomes covid + we will follow the recommendations for cleaning and disinfecting that are detailed in her plan at the following link to ensure the health of the entire team.  [University, Environmental Health and Safety](https://www.uhs.umn.edu/sites/uhs.umn.edu/files/cleaning_work_spaces.pdf) **This plan was developed in consultation with the department head and the CMRR approval committee since my work is done under the auspices of the Department of Medicine and 2 of my 4 protocols are done in the CMRR.** |

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| 1. Social distancing between employees must be maintained at all times. **Please describe any occasions where you will not be able to maintain 6 ft between employees in clinical research or general office spaces and how you are ensuring the safety of employees in these instances (e.g. PPE use).**
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| As much as possible during research study visits, only one member of the research team (CRU staff, coordinator, PI/Co-I) will be in the same room as the study participant and social distance will be maintained when able. Social distancing will also be practiced between research team members as much as possible.* In person meetings of employees will not be held during the **Sunrise Steps 1 or 2.**
* Meals will not be eaten together during **Sunrise Steps 1 or 2.**
* Handwashing practices will be carefully attended by thorough washing with soap after tasks are completed.

**This plan was developed in consultation with my department head and the CMRR approval committee since my work is done under the auspices of the Department of Medicine and 2 of my 4 protocols are done in the CMRR.****The specific plans for each protocol are described below.****GRADE study (IRB# \_\_\_\_\_\_\_\_):** Subjects will need to be seen face to face to complete data collection on annual and semiannual visits. Staff need to obtain vitals, do foot exams, collect blood via venipuncture, collect filled urine cups, insert an IV for sample collection during an oral glucose tolerance tests at a distance from the subject of less than 6 feet. During these visits staff will wear masks and eye shields, subjects will wear masks, and time of the interaction will be minimized (anticipate less than 10 minutes on semiannual visits and 20 minutes on annual visits). In addition, the staff will divide up the work so that one does the sample collection and the other does the vitals and exam. This will minimize the time a staff person is less than 6 feet from a subject. While in the DCRU staff will remain more than 6 feet apart.**Exercise study (STUDY\_\_\_\_\_\_\_\_):** In this study, subjects have a screening visit in which consent is obtained and a continuous glucose monitor is applied that is followed in one week by two days of experimental measures. On the first day they perform two 90-minute periods of exercise on an exercise bike during which they are clamped at euglycemia and on the second day they undergo a hypoglycemic clamp. During the clamp studies, our nurses will often be less than 6 feet from the research subject as they collect blood every 5 minutes for up to 3 hours. During the exercise, they are monitored by an exercise technician who will often be less than 6 feet from the research subject We will provide masks and eye shields for the nurses and technicians to wear at all times. Subjects will be asked to wear the masks while in the CRU. As much as possible, study personnel and study equipment will be moved to ensure that everyone who can be 6 feet apart will be. Specifically, the glucose analox necessary for bedside glucose measurement will be set up in a different but adjacent room, the infusion pumps will be equipped with extra IV tubing so they can be more than 6 feet from the subject. **3T Aim 1 (STUDY\_\_\_\_\_\_\_\_\_\_):** In this study, subjects undergo five clamp studies over 3 days. Three are done in the CMRR (two in the 3T magnet) and two are done in the CRU. During the clamp studies, our nurses will often be less than 6 feet from the research subject as they collect blood every 5 minutes for up to 3 hours. We will provide masks and eye shields for the nurses to wear at all times. Subjects will be asked to wear the mask when they are out of the magnet but allowed to take it off if they wish when they are in the magnet. While in the CMFR and CRU staff will remain more than 6 feet apart. As much as possible, study personnel and study equipment will be moved to ensure that everyone who can be 6 feet apart will be. Specifically, the glucose analox necessary for bedside glucose measurement will be set up in a different but adjacent room, the infusion pumps will be equipped with extra IV tubing so they can be more than 6 feet from the subject. This study also requires a screening visit where a continuous glucose monitor and an actigraph are applied to the patient by study personnel. This will require the subject and the study person to be closer than 6 feet. We will provide masks and eye shields for the nurses to wear at all times. Subjects will be asked to wear a mask.**7T aim 2 (STUDY\_\_\_\_\_\_\_\_\_\_\_\_\_):** This study has a similar design as the 3T aim 1 study (although only 4 clamps are done over 2 days) and has the same requirements for subject and study personnel to sometimes be less than 6 feet from each other. In this protocol, subject undergo two clamp studies per day (one in the clinical research space at the CMRR and one in the 7T magnet) on two consecutive days. We will follow the same procedures as listed for the 3T aim 1 study. |
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| 1. Please describe any electronic scheduling/calendaring mechanisms to minimize face-to-face contact among employees in a non-clinical setting.
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| All on campus work will be **coordinated via Google calendar** for safety (shared among portfolio personnel members), indicating location and times. Use of this calendar will be **mandatory** for every on-site work encounter. |

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| 1. Please describe your processes to disinfect surfaces in space shared/used by multiple employees in non-clinical spaces.
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| At the end of their shift, each employee will disinfect their workspace and the common equipment that they used. In addition, the shared workspace will be disinfected twice daily by a designated lab or section member. Emphasis will be on high-touch surfaces. We will use an approved disinfectant 70% ethanol, left on the surface for 1 minute. A checklist of all required areas to be cleaned will be sent to each employee electronically to ensure no areas are overlooked. The PI is responsible for ensuring cleaning supplies are in place for employees. **This plan was developed in consultation with the department head.**In the CMRR, University custodial staff will be disinfecting and cleaning common areas (restrooms, door handles, etc.), but employees/researchers will be expected to disinfect ALL other surfaces that you come into contact with using provided 70% alcohol mist or disinfecting wipes. We will disinfect the bore of the scanner, scanner table, coils, counters, keyboards, any shared equipment or supplies, cabinet door handles, etc. We will work under the assumption that surfaces and shared equipment have not been properly disinfected and will disinfect both prior to use and after use. Positioning foam used in the magnets will have a non-porous wipeable surface. **This plan was developed in consultation with the CMRR.** |

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| **Section C: PI’s/Research Team’s Clinical Research Sunrise Strategy** |
| Please provide a brief overview of the strategy you will use to resume face-to-face interactions with participants across your entire portfolio within each Clinical Research Sunrise Step. Detailed information on each protocol is not required in this section.**Sunrise Step 1:** |
| Sunrise Step 1 may approach 50% of pre-COVID-19 face-to-face interactions with participants. Please describe your overarching plan to meet this metric. Include a discussion of how you will mitigate staff and participant risk and prioritize work within your portfolio based on the immediacy of projects, strategic value, funding, standard of care, etc. Discuss how PPE will be procured by the PI/research team for research visits and other needs. If you are submitting your plan as a research group, please discuss how you will prioritize work across the entire team (i.e. which work will you sunrise first and why). |
| **Please see the table at the end of the application that lists the hours employees will be permitted to work on site doing this research during each Sunrise Step. In Step one, we will limit the hours to less than 50% of our pre-covid face to face interactions with participants.**1. We will first start seeing subjects in the GRADE study. This study is our highest priority because study closeout is approaching and the integrity of the trial requires collection of blood and urine samples that can only be done in person. In addition, it is critical we retain the subjects until the end and many are expressing the strong preference to return in person. Supporting the preference of the research subject is critical to subject recruitment. The protocol requires approximately 300 visits over the next 6 months and fewer over the subsequent 12 months as the study wraps up. We propose to do only the annual and semiannual visits (about 150 over the next 6 months). Staff need to obtain vitals, do foot exams, collect blood via venipuncture, collect filled urine cups, insert an IV for sample collection during an oral glucose tolerance tests at a distance from the subject of less than 6 feet. During these visits staff will wear masks and eye shields, subjects will wear masks, and time of the interaction will be minimized (anticipate less than 10 minutes on semiannual visits and 20 minutes on annual visits). In addition, the staff will divide up the work so that one does the sample collection and the other does the vitals and exam. This will minimize the time a staff person is less than 6 feet from a subject. While in the DCRU staff will remain more than 6 feet apart.2. We also propose to start one of the CMRR based protocols during Step 1. If the 7 Tesla magnet is fully operational, we will start with the 7T aim 2 but if it is not, we will start with 3T aim 1. Our preference is to do the 7T study because we are halfway through data collection and will never be able to use the data if the sample size is not increased. The 7T magnet has been undergoing an upgrade for the last several months which has put this study on hold. It is nearing completion of the upgrade. We anticipate it will be operational by the time the sunrise plan is approved. If it is not, it is likely that it will be some time before we can use the 7T magnet. If that is true, we will proceed with the 3T study. Both are funded by the RO1 to Drs. Seaquist/Oz. The progress on this grant has been greatly impacted by covid so starting up either protocol will be necessary to catch up with our timeline.Whichever of the two protocols we are allowed to start in Step 1, we will plan to do no more than one screening visit and one set of clamp experiments in and outside of the magnet each week. This will mean that one subject will have a screening visit each week and one will undergo the 2-3-day experimental protocol. During the clamp studies, our nurses will often be less than 6 feet from the research subject as they collect blood every 5 minutes for up to 3 hours. We will provide masks and eye shields for the nurses to wear at all times. Subjects will be asked to wear the mask when they are out of the magnet but allowed to take it off if they wish when they are in the magnet. While in the CMFR and CRU staff will remain more than 6 feet apart. As much as possible, study personnel and study equipment will be moved to ensure that everyone who can be 6 feet apart will be. Specifically, the glucose analox necessary for bedside glucose measurement will be set up in a different but adjacent room, the infusion pumps will be equipped with extra IV tubing so they can be more than 6 feet from the subject. This study also requires a screening visit where a continuous glucose monitor and an actigraph are applied to the patient by study personnel. This will require the subject and the study person to be closer than 6 feet. We will provide masks and eye shields for the nurses to wear at all times. Subjects will be asked to wear a mask.**We will purchase PPE for staff and research subjects and disinfectant from Ustores. We will monitor supply to ensure we have sufficient PPE for planned work. If PPE becomes unavailable, we will not do our studies.**  |
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**Sunrise Step 2:**

Sunrise Step 2 may approach 75% of pre-COVID-19 face-to-face interactions with participants. Please describe your overarching plan to meet this metric. Include a discussion of how you will mitigate staff and participant risk and prioritize work within your portfolio based on the immediacy of projects, strategic value, funding, standard of care, etc. Discuss how PPE will be procured by the PI/research team for research visits and other needs. If you are submitting your plan as a research group, please discuss how you will prioritize work across the entire team (i.e. which work will you sunrise first and why).

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| **Please see the table at the end of the application that lists the hours employees will be permitted to work on site doing this research during each Sunrise Step. In Step two we will limit the hours to less than 75% of our pre-covid face to face interactions with participants.**1. During step 2 we will begin to do one screening visit and one of the two-day clamp studies for the exercise study each week. This means that one subject will undergo a screening visit and one undergo the two days of clamps each week. During the clamp studies, our nurses will often be less than 6 feet from the research subject as they collect blood every 5 minutes for up to 3 hours. During the exercise, they are monitored by an exercise technician who will often be less than 6 feet from the research subject We will provide masks and eye shields for the nurses and technicians to wear at all times. Subjects will be asked to wear the masks while in the CRU. As much as possible, study personnel and study equipment will be moved to ensure that everyone who can be 6 feet apart will be. Specifically, the glucose analox necessary for bedside glucose measurement will be set up in a different but adjacent room, the infusion pumps will be equipped with extra IV tubing so they can be more than 6 feet from the subject. **We will purchase PPE for staff and research subjects and disinfectant from Ustores. We will monitor supply to ensure we have sufficient PPE for planned work. If PPE becomes unavailable, we will not do our studies.**  |
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**Sunrise Step 3:**

Essentially full operations approaching 100% workforce return. Discuss increased areas of activity.

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| **Please see the table at the end of the application that lists the hours employees will be permitted to work on site doing this research during each Sunrise Step. In Step three, we will be back to 100% our pre-covid face to face interactions with participants.**During step 3, we will begin the magnet-based study not started in step 1. Each week this will involve doing one screening visit and 2-3 days of clamp studies on one subject.**We will purchase PPE for staff and research subjects and disinfectant from Ustores. We will monitor supply to ensure we have sufficient PPE for planned work. If PPE becomes unavailable, we will not do our studies.**  |
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Summary of work hours for employees working on this portfolio of projects

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| --- | --- | --- | --- | --- |
| Employee | Current hours/week doing research work on site | Step 1 hours/week doing research work on site | Step 2 hours/week doing research work on site | Step 3 hours/week doing research work on site |
| NAME |   |   |   |   |
| 0 | 10 | 10 | 15 |
| NAME | 0 | 4 | 4 | 4 |
| NAME \* | 20 | 20 | 30 | 40 |
| NAME | 0 | 8 | 10 | 20 |
| NAME | 0 | 4 | 4 | 4 |
| NAME\* | 8 | 18 | 26 | 30 |
| NAME\* | 16 | 20 | 24 | 40 |
| NAME\* | 20 | 20 | 30 | 40 |
| NAME | 0 | 0 | 10 | 20 |
| NAME | 0 | 6 | 10 | 20 |
| NAME | 0 | 6 | 10 | 20 |
| NAME\* | 4 | 4 | 4 | 4 |
| NAME | 0 | 4 | 5 | 15 |
| NAME \* | 20 | 20 | 30 | 40 |
| NAME | 0 | 20 | 20 | 40 |
| NAME\* | 4 | 20 | 20 | 40 |
| Total hours | 92 | 184 | 247 | 392 |
| \* employees already approved to do on site research work |  |  |  |  |
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| **Section D: Protocol-Specific Details** |

Please complete the “Protocols in Portfolio” tab in the Data Form to submit details on each protocol within this Portfolio Plan. In addition, if the Portfolio Plan requires in-person monitor visits, please complete the “Monitor Visits” tab in the Data Form.

I confirm that I understand the requirements set forth by the Office of the Vice President for Research and the Medical School. I affirm that the proposed Portfolio Plan can be conducted in a safe manner that protects participants, research, and the community, and minimizes person-to-person interaction per the considerations outlined in [Human Research: Latest IRB Guidance and FAQ (COVID-19)](https://drive.google.com/file/d/1YeITEX78l9exIm7GGdtHyQlfL9xclAhT/view). I understand conditions may change that would cause the research to revert to a reduced level of activity.

PI SIGNATURE June 22, 2022

**PI/Research Group Leadership Signature Date**

Department Head or OACA Center Director Signature 6/22/2020

**Medical School Department Head or OACA Center/Institute Director Signature Date**