OVCGRE / SMPH / VA / DOM Restart Research Process

All Divisional personnel who will be working on campus (at either a UW building, off-campus building, or at the VA hospital) are required to be approved for working on campus. In addition, all in-person human subject research studies are required to be approved prior to restarting. The following steps will help walk you through the process and expectations for timeline approval.

Go to this location to receive access to all forms, guidelines, and COVID signage: \G:\Team\Geriatrics General\Restart Research Forms. If you do not have access, please contact Toni Hofhine (thofhine@medicine.wisc.edu) to request access.

Phase 1 Restart Research Process – Studies and Personnel Approval

Consider current UW social distancing requirements and current personnel already working in the space your personnel will be working in.

1. Complete the form (PI OVCRGE Phase 1 and 2 Form Template.docx).
2. Contact the following people to obtain approval on spaces available within social distancing to complete the form:

<table>
<thead>
<tr>
<th>Space</th>
<th>Contact Name</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA GRECC</td>
<td>Charity Frey</td>
<td><a href="mailto:Charity.Frey@va.gov">Charity.Frey@va.gov</a></td>
</tr>
<tr>
<td>K6/4</td>
<td>Amy Hawley</td>
<td><a href="mailto:ahawley@medicine.wisc.edu">ahawley@medicine.wisc.edu</a></td>
</tr>
<tr>
<td>K6/3</td>
<td>Toni Hofhine</td>
<td><a href="mailto:thofhine@medicine.wisc.edu">thofhine@medicine.wisc.edu</a></td>
</tr>
<tr>
<td>Division Office</td>
<td>Toni Hofhine</td>
<td><a href="mailto:thofhine@medicine.wisc.edu">thofhine@medicine.wisc.edu</a></td>
</tr>
<tr>
<td>J5/MEZZ</td>
<td>Hanna Blazel</td>
<td><a href="mailto:hmb@medicine.wisc.edu">hmb@medicine.wisc.edu</a></td>
</tr>
<tr>
<td>3330 University Ave</td>
<td>Hanna Blazel</td>
<td><a href="mailto:hmb@medicine.wisc.edu">hmb@medicine.wisc.edu</a></td>
</tr>
</tbody>
</table>

3. Send your completed form to Julie Hyland (jdhyland@medicine.wisc.edu) and Toni Hofhine (thofhine@medicine.wisc.edu).
4. The approval processes will be completed by Julie and Toni:
   a. Toni reviews form for completeness and space with social distancing compliance.
   b. Julie sends reviewed forms to Dr. Sanjay Asthana and cc to Toni Hofhine for UW approvals.
   c. Julie saves files to G:\Team\Geriatrics Administration\Research\2020 Post COVID.
   d. Julie sends reviewed forms to Dr. Nasia Safdar and cc to Toni Hofhine and Charity Frey for VA approvals.
   e. When approvals come through, Julie completes online forms.
5. Julie sends an email to Sharon Gehl (slgehl@medicine.wisc.edu) with the approved form attached to receive DOM approval for personnel to work on-campus.
   a. When approval is given by Sharon, fill out the form here: https://uwmadison.co1.qualtrics.com/jfe/form/SV_eQWTWMMDzuQxc0d.
6. Julie sends email approval to PM/PI of who is approved to work on-campus, so they are aware approval for on-site campus work has been granted.
   a. Sends email to each individual approved to work on campus, with a copy to the Program Manager and/or Faculty PI, as well as Toni Hofhine to ensure that each person understands the expectations and training requirements
   b. Julie will update the DOM HR tracking form here with blue text for all new approvals and tracking of who has received email letters (G:\Team\Geriatrics Administration\Research\2020 Post COVID\DOM List).
7. All personnel approved to work on campus must follow the information contained within the following documents located here: G:\Team\Geriatrics General\Restart Research Forms.
   b. COVID Signage.zip
   c. FPM Public Health Protocols Phase 1 Research Reopening.pdf
   d. Research Restart_ PI Message from OVCRGE.pdf
Note: As of April 2, 2021, SMPH has retired the Phase 2 Restart of Clinical Research for new and on-going studies

Phase 2 Restart Research Process—Studies and Personnel Approval

All in-person human research studies at the VA and/or SMPH require approval prior to resuming in-person study research activities. Please follow the steps below, referencing all documents stored here: G:\Team\Geriatrics General\Restart Research Forms\UW Restart Research.

Below are the steps for submitting SMPH Phase 2 human subject research studies:

2. Complete the form (Phase 2 In Person Human Research Form.xlsx) for each human subject research study you wish to have reviewed for restart approval.
3. Send your xlsx forms to Julie Hyland (jdhyland@medicine.wisc.edu) and Toni Hofhine (thofhine@medicine.wisc.edu).
4. The approval processes will be completed by Julie and Toni:
   a. Toni reviews form for completeness.
   b. Julie saves files to G:\Team\Geriatrics Administration\Research\2020 Post COVID
   c. Julie sends reviewed forms to Dr. Sanjay Asthana and cc to Toni Hofhine for UW approvals.
   d. Once approved by Dr. Asthana, Julie sends form to Rochelle Rannow (rochelle.rannow@wisc.edu) and cc Toni Hofhine for final Dean’s office approval.
   e. Julie sends Phase 2 approval to Program Manager and PI, with a reminder to follow the Phase 1 Restart Research Process for personnel approval to work on campus.
5. All personnel who need to work on campus for the in-person human research study must have pre-approval to work on campus. Follow the Phase 1 Restart Research Process—Studies and Personnel Approval process from #1-6.
6. If you have a dual SMPH and VA human subject research study you would like to have restarted for in-person activities, see the steps below outlined for VA ONLY human subject research study restart.—
Below are the steps for submitting VA ONLY human subject research study restart:

If you have a VA human subjects research project open with an IRB and the VA R&DC you would like to have restarted for in-person activities, please follow the steps below, referencing all documents stored here: G:\Team\Geriatrics General\Restart Research Forms\VA Restart Research.

1. Complete the Investigator COVID Risk Assessment and ACOS decision v3.pdf form for each study in which there is any need for in-person human subject contact of any kind, including:
   - Physical exams, vital signs, blood draws, EKGs, MRI and CT scans, etc.
   - Assessments that require in-person attendance (e.g., cognitive memory testing)
   - Research that relies on obtaining biological samples from patients during an existing clinical visit
   - Research that relies on observation of and/or consent to enroll clinical hospital staff

   **Note from ORD:** The risk assessment should take into consideration that the COVID-19 pandemic may change the risk level to participants based on potential co-morbidities that would increase the risk of illness if exposed to SARS-CoV-2; the risk of the study procedures to participating subjects; and the potential of increased exposure to study staff or others in the medical center. The assessment should include a thoughtful summary of how you intend to mitigate these risks.

   **AND/OR**

2. Complete the Waiver of VA ORD Investigator COVID-19 Risk Assessment.pdf form listing all studies in which the following may be true:
   - Study is medical records research only
   - Study has completed enrollment and is continuing with data analysis only
   - Study which conducts assessments or interviews with human subjects but there is no in-person contact required to conduct these research activities

   **Note:** Please provide as much detail as possible in your risk assessment and/or waiver applications. The R&DC will review and approve all applications to resume human subject research activities. If there is insufficient detail provided for the R&DC to make a determination, your application will be deferred to the next meeting and resumption of your research activities will be delayed.

   There is a question surveying the PPE needs for your study team in both the Risk Assessment and the Waiver forms. Please try to be as accurate as possible in your estimates. The estimates should be based upon PPE that are needed above and beyond what is already being provided by the hospital to employees and service lines.

3. Submit these forms to Aaron Heneghan (Aaron.Heneghan@va.gov) with a copy to Charity Frey (Charity.Frey@va.gov).

4. Aaron Heneghan will send email approval with additional safety guidelines once your submittal has been reviewed. Note that all VA study approvals require UW SMPH personnel to adhere to both VA and SMPH restart research safety guidelines.

5. All personnel who need to work on campus for the in-person human research study must have pre-approval to work on campus. Follow the Phase 1 Restart Research Process – Studies and Personnel Approval process from #1-6.
Changes to Personnel Working on Phase 1 and 2 Research

Please follow the steps below, referencing all documents stored here: G:\Team\Geriatrics General\Restart Research Forms\UW Restart Research. All personnel who are already approved for on-campus research (at either a UW building, off-campus building, or at the VA hospital) and either depart the Division of Geriatrics or increase/decrease their time on campus AND all personnel who are newly hired and need to be on-campus for research at the VA and/or SMPH require approval prior to resuming in-person study research activities.

1. Follow the Phase 1 Restart Research Process – Studies and Personnel Approval process from #1-6.