Phase 2+ Exception Request for Off-Campus Research Form

Please read all instructions before completing the form below.

Phase 2+ Exception Request for Off-Campus Research Form

INSTRUCTIONS:

This form enables lead researchers to request an exception to travel locally within Metro Nashville and its immediate environs or domestically within the continental U.S. beyond the Metro Nashville area for the purpose of performing research activities. This includes research activities that may involve research participants (aka human subjects). Please note that in this phase of research ramp-up as in all other phases, all gatherings, travel, and off-campus research activities must abide by VU guidelines.

This form can be completed instead of or in addition to the separate Phase 2+ Intake Form, which covers a range of research activities to be performed on-site at Vanderbilt.

Using the COVID-19 Related Safety Guidelines for Research Ramp-up as a resource, please complete the requested information to the best of your ability.

For any questions that do not apply to you and your research, simply reply "N/A."

You may not see/answer all possible items on this form. This is deliberate. In order to keep this form as short as possible for each respondent, built-in branching logic ensures you are asked only the items that are relevant to your Phase 2+ exception research activities based on your answers to previous items. For this reason, you may notice that the items on this form do not proceed in normal numbered order. For example, you may answer items 1-5, but then skip to item 8. If this happens to you, do not be alarmed; unusual numbering is a normal side-effect of the built-in branching logic.

If additional information or documentation is required, you will be contacted separately. You will be notified of approval as soon as practicable, including the date on which you may resume on-campus research activities, as well as any special requirements or limitations.

RESEARCH ACTIVITIES COVERED IN THIS FORM:

This form covers off-campus research activities only. "Off-campus" research activities are defined as research activities that occur in spaces that fulfill both of the following criteria: NOT owned, operated, and/or leased by VU or VUMC NOT individual VU community members' own homes in use as remote workspaces Examples of such spaces within Metro Nashville and its immediate environs include Metro Nashville K-12 schools, Andrew Jackson State Office Building, the Adventure Science Center, non-VU community members' own homes Examples of such spaces in the continental U.S. outside of Metro Nashville include Oak Ridge National Laboratory in east Tennessee, the Ohio State University in Ohio, the National Archives Research Center in Washington, D.C., McDonald Observatory in Texas This form covers...
off-campus research activities that do or do not involve research participants (aka human subjects). OTHER RESEARCH ACTIVITIES NOT COVERED IN THIS FORM:

Research activities that are permissible in Phase 2+ through the completion, review, and approval of the separate Phase 2+ Intake Form: On-site research area occupancy increases to < 50% and in certain cases may increase to < 70% when necessary provided that the COVID-19 Related Safety Guidelines for Research Ramp-up are strictly followed including maintaining 6 ft. distancing between research team members, wearing face masks, and so on. We strongly encourage lead researchers to maintain research area occupancy at no more than 50% in Phase 2+ for the safety of our research community. Undergraduate involvement is permitted in on-site research activities. Lead researchers are permitted to host visiting researchers on-site. "Visiting researchers" are narrowly defined as research collaborators who fulfill all of the following criteria: Do not have a formal affiliation with Vanderbilt University Do not have a VUnet ID Are not visiting campus as part of an interview for a faculty or postdoctoral position at Vanderbilt Do engage in research activities that are subject to the VU research ramp-up review and approval process Research activities involving research participants (i.e., human subjects) is permitted on-site. Research activities that are permissible in Phase 2+ but do NOT require the completion, review, and approval of this Phase 2+ Exception Request for Off-Campus Research Form or the separate Phase 2+ Intake Form: Research activities that are conducted strictly through remote means with research team members (faculty, staff, postdoctoral fellows, graduate students, and/or undergraduate students) working separately within their individual homes and engaging only virtually do NOT require a Phase 2+ Intake Form or Phase 2+ Exception Request for Off-Campus Research Form. Research activities that were previously approved through a Phase 1 or 2 Intake Form or Phase 1 or 2 Exception Request and have not changed do NOT require a the completion of a new Phase 2+ Intake Form or Phase 2+ Exception Request for Off-Campus Research Form. If your plans have changed since they were approved in a previous phase, you must complete a new Phase 2+ Intake Form and/or PPhase 2+ Exception Request for Off-Campus Research Form and receive a new approval to proceed with implementing those changes. If you’re not sure which form(s) to complete in order to proceed with your intended research activities, please contact ovpr@vanderbilt.edu for guidance.

1. School/college
   - Blair School of Music
   - College of Arts and Science
   - Graduate School (select this option if you are a VUMC PI mentoring a VU grad student)
   - Law School
   - Owen School of Management
   - Peabody College of Education and Human Development
   - School of Engineering
   - School of Medicine - Basic Sciences
   - School of Nursing
   - Trans-institutional research center or institute reporting to the Vice Provost for Research

2. Department name

3. Department chair name (first, last)
4 Lead researcher (mentor/PI) given (first) name

In the case of a research center or institute, this would be the director's given name.

5 Lead researcher (mentor/PI) family (last) name

In the case of a research center or institute, this would be the director's family name.

6 Lead researcher (PI/mentor) Vanderbilt email address

For example:

john.doe@vanderbilt.edu

7 Is the lead researcher a faculty member who is dual-employed by VU and VUMC (i.e., the lead researcher has a faculty appointment with VU as well as a separate appointment with VUMC)?

- Yes, the lead researcher is dual-employed by VU and VUMC.
- No, the lead researcher is NOT dual-employed by VU and VUMC.

8 Project name and description

9 Have you previously submitted any of the following forms associated with VU's phased research ramp-up? Check all that apply.

- I previously submitted a Phase 1 intake form.
- I previously submitted a Phase 2 intake form.
- I previously submitted a Phase 2+ intake form.
- I previously submitted an exception request in Phase 2.
- I have not previously submitted any of the above forms.

10 Why do these research activities need to occur off-campus instead of on-campus?

11 Are you requesting to perform research activities with research study participants (aka human subjects)?

Examples:

- Yes, I am requesting off-campus research activities involving research study participants.
- No, I am requesting off-campus research activities that do NOT involve research study participants.
**RESEARCH PARTICIPANTS (HUMAN SUBJECTS) SECTION**

If you are not performing research activities with research participants (human subjects), this section will be blank.

12 Does the study IRB need to be modified to address significant changes in the research protocol due to COVID-19 accommodations?

- [ ] Yes, the IRB requires modification related to COVID-19 accommodations.
- [ ] No, the IRB does NOT require modification related for COVID-19 accommodations.

Note that the required pre-screening questions do not require IRB modification.

Refer to the IRB website for important updates and instructions regarding the need for IRB amendments (https://www.vumc.org/irb/covid-19-updates-research). Please note that clicking this link will route you away from this page; we recommend opening the link in a separate tab or window either by right-clicking the link or copying and pasting the url into a separate tab or window.

13 Will research participants have visitors (e.g., parent/guardian, aide, etc.) present during the study visit?

- [ ] Yes, visitors will be present with research participants.
- [ ] No, visitors will NOT be present with research participants.

14 What general timeframes do you expect research participants to be engaging with your team in your research activities? Check all that apply.

- [ ] Weekdays (Mon.-Fri.) during business hours (8AM-5PM)
- [ ] Weekdays (Mon.-Fri.) outside business hours (before 8AM, after 5PM)
- [ ] Weekends (Sat.-Sun.) during business hours (8AM-5PM)
- [ ] Weekends (Sat.-Sun.) outside business hours (before 8AM, after 5PM)

15 How many research participants do you estimate for this project per week?

__________________________________
16 List all VU PERSONNEL (i.e., faculty, staff, postdoctoral fellows, graduate students, and undergraduate students) who will be working in off-campus location.

Please designate each person's role (i.e., faculty, staff, postdoctoral fellow, graduate student, or undergraduate student), their frequency of off-campus duties, and specify where they will be working (i.e., which location(s) listed in the previous question).

Please use the format of the following example in your answer, with one person per line:

Doe, John (Graduate Student) 4000 Imaginary Lane, Los Angeles, CA 90029, every two weeks

Smith, Alice (Faculty Member) 101 Fake Drive, Cincinnati, OH 45224, once month

17 How many total research personnel will be engaged in research activities off-campus for this project in Phase 2+?

18 Of all the Phase 2+ research personnel listed above, which personnel will be interacting/engaging in research activities with research participants off-campus?

Please include all of the following information for each person listed:

Full name (Last, First) Role (Faculty Member, Staff Member, Graduate Student, etc.) Location (building, room) Please use the format of the following example in your answer, with one person per line:

Doe, John (Graduate Student) Shangri-La Elementary School, 4000 Imaginary Lane, Nashville, TN 37214
Smith, Alice (Faculty Member) Dover Hall, Room 555, Pimiento University, 101 Fantasy Terrace, Boston, MA 02134

19 Are any of your research personnel listed above postdoctoral fellows, graduate students, or undergraduate students? Check all that apply.

☐ Some of my research personnel are postdoctoral fellows and/or graduate students.
☐ Some of my research personnel are undergraduate students.
☐ NONE of my research personnel are postdoctoral fellows, graduate students, or undergraduate students.
20 Of all the Phase 2+ research personnel listed above, which personnel are UNDERGRADUATE STUDENTS?

Please include all of the following information for each person listed:

Full name (Last, First) Role (Undergraduate Student) Location (building, room) Please use the format of the following example in your answer, with one person per line:

Doe, John (Undergraduate Student) Vanderbilt Hall, Rooms 200 and 201

If your Phase 2+ research personnel includes no undergraduate students, please mark this item "N/A".

21 Describe the undergraduate student(s) listed above and their role in your research activities. Address all of the following considerations in your answer:

Anticipated duties and responsibilities Participation in VU's undergraduate Immersion program Level of experience in research activities (e.g., is this undergraduate student participating in research activities/joining your research team for the first time?) Level of training and/or supervision that will be needed for the undergraduate research personnel to perform research activities safely

22 Select the school or college in which the undergraduate student(s) you've listed are enrolled. Check all that apply.

Examples:

If you have 1 undergraduate student who is enrolled in the neuroscience program within the College of Arts and Science, select College of Arts and Science only. If you have 1 undergraduate student who is a dual-major in neuroscience within College of Arts and Science and child development within Peabody College, select both College of Arts and Science and Peabody College. If you have 2 undergraduate students, 1 who is enrolled in the biomedical engineering program within the School of Engineering and 1 who is enrolled in the neuroscience program within the College of Arts and Science, select both School of Engineering and College of Arts and Science.
RESEARCH SPACE AND PROTOCOLS SECTION

23 List all off-campus research setting locations (i.e., research travel destinations). For each location, include full address with city, state, and zip code. 

If applicable, include building and room number(s).

24 Describe the research activity/activities in the off-campus research site and how the COVID-19 Related Safety Guidelines for Research Ramp-Up will be addressed. Answer the following questions in your response:

What precautions will you take to ensure the safety of yourself and/or other research staff in the off-campus research sites (prior to entering and once in the location)? Include steps taken prior to arrival at the off-campus site, while working at the off-campus site, and after leaving the off-campus site (e.g., how and where PPE will be disposed). Are there any "No-go" triggers you have established for this project? "No-go" triggers are any instances when upon arrival you would determine it is not safe for research personnel to enter the location and abort or suspend the planned research activities until safety can be ensured. If your research activity requires 2 or more people to be in closer proximity than six (6) feet and detail your plans for managing these interactions.

25 What additional precautions will you take to ensure the safety of research participants (human subjects) who will be engaging in research activities in the off-campus research site? Refer to the COVID-19 Related Safety Precautions for Research Participants for guidance.

In your answer, address all of the following:

Steps taken prior to arrival at the off-campus research site to ensure safety Steps taken on the off-campus research site during research activities to ensure safety "No-go" triggers, i.e., any instances when you would determine it is not safe for the research participants (human subjects) for research personnel to enter the location and abort or suspend the planned research activities until safety can be ensured.

26 Please list any additional COVID-19 safety precautions that you intend to implement in the off-campus research site during your visit (e.g., entry/exit procedures, PPE disposal, use of disposable computer keyboard covers, etc.). (optional)
<table>
<thead>
<tr>
<th>27</th>
<th>If applicable, have you received and reviewed the COVID-19 safety protocols for the organization you propose to visit?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The organization I propose to visit has COVID-19 safety protocols, and I have received and reviewed them.</td>
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<tr>
<td></td>
<td>I have requested COVID-19 safety protocols from the organization, but have not yet received them.</td>
</tr>
<tr>
<td></td>
<td>The organization I propose to visit does NOT have COVID-19 safety protocols.</td>
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</table>

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<tr>
<th>28</th>
<th>Do you agree to follow whichever organization's protocols and safety precautions are more stringent?</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>YES, I agree to follow whichever organization's protocols and safety precautions are more stringent.</td>
</tr>
<tr>
<td></td>
<td>NO, I do NOT agree to follow whichever organization's protocols and safety precautions are more stringent.</td>
</tr>
</tbody>
</table>

In effect:

If Vanderbilt University's protocols and safety precautions are more stringent than those of the off-campus organization you will visit, you will follow Vanderbilt University's protocols and safety precautions. If the protocols and safety precautions of the off-campus organization you will visit are more stringent than Vanderbilt University's, you will follow the protocols and safety precautions of the off-campus organization.

<table>
<thead>
<tr>
<th>29</th>
<th>Please refer to the COVID-19 Related Safety Guidelines for Research Ramp-up. Do you agree to implement these precautions?</th>
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<tbody>
<tr>
<td></td>
<td>Yes, I agree to implement these precautions.</td>
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<tr>
<td></td>
<td>No, I do NOT agree to implement these precautions.</td>
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<tr>
<th>30</th>
<th>The COVID-19 Related Safety Guidelines for Research Ramp-up provides guidance on how to procure personal protective equipment (PPE) such as masks.</th>
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<tr>
<td></td>
<td>Yes, I have at least 2 weeks' worth of PPE available.</td>
</tr>
<tr>
<td></td>
<td>No, I have does NOT have at least 2 weeks' worth of PPE available.</td>
</tr>
</tbody>
</table>

Having followed this guidance, do you have sufficient PPE available to last for the full duration of the planned off-campus research activities?

Remember to account for your full research team and research participants (if applicable) in your PPE preparations.

Please note that clicking this link will route you away from this page; we recommend opening the link in a separate tab or window either by right-clicking the link or copying and pasting this url (https://research.vanderbilt.edu/vu-covid-19-related-safety-guidelines-for-research-ramp-up/) into a separate tab or window.

You have reached the end of the Phase 2+ Exception Request for Off-Campus Research Form.

To submit this completed form for review by the Ad Hoc Research Ramp-up Working Group, your dean's office, and the Provost, click SUBMIT below. To save this form and return to it later, click SAVE & RETURN LATER. This will NOT send your form to the Ad Hoc Research Ramp-up Working Group, your dean's office, or the Provost. By clicking either option:

You will have the opportunity to save a personalized return code and send a personalized survey link to your email address to enable you to return to this form to revise your responses and/or (re)submit your form for review. You will have the opportunity to download a PDF of your responses to this form.